III. What are we proposing Today?

We are proposing, and requesting comment upon, public health and safety standards governing the storage and disposal of SNF, HLW, and other radioactive material in the repository at Yucca Mountain, Nevada. We are also announcing a public comment period and public hearings to gather comments upon the proposal.

As noted earlier, section 801(a)(1) of the EnPA gave us rulemaking authority to set "public health and safety standards for the protection of the public from releases from radioactive materials stored or disposed of in the repository at the Yucca Mountain site." The statute also directed us to develop standards "based upon and consistent with the findings and recommendations of the National Academy of Sciences." Section 801(a)(2) of the EnPA directed us to contract with NAS to conduct a study to provide findings and recommendations on reasonable standards for protection of the public health and safety. Because the EnPA called for us to act "based upon and consistent with" the NAS findings, a major issue in this rulemaking is whether we are bound to follow the NAS determinations without exception or whether we have discretionary decision-making authority.

As a practical matter, the difficulty of this issue is reduced because some of the findings and recommendations in the NAS Report are expressed in a non-binding manner. In other words, NAS stated its findings and recommendations as starting points for the rulemaking process or recognized those that involve public policy issues that are more properly addressed in this public rulemaking proceeding. However, the Report also contains some findings and recommendations stated in relatively definite terms. It is these issues that most squarely present the question of whether we are to treat the views of NAS as binding.

Whether the EnPA binds us to following exactly the NAS findings and recommendations is a question that warrants close attention at this stage of the rulemaking because it affects the scope of our rulemaking. If we are required to follow every view expressed in the NAS Report, any such issue would be treated as addressed conclusively by NAS. We would not need to entertain public comment upon the affected issues since the outcome would be predetermined.

We believe that the EnPA does not bind us absolutely to follow the NAS Report. Instead, we have used the NAS Report as the starting point for this rulemaking. Today's proposal is based upon and consistent with the findings and recommendations of NAS. We have developed this proposal guided by the findings and recommendations of NAS because of the special role given NAS by Congress and the scientific expertise of NAS. However, the entirety of our proposed standards for the Yucca Mountain disposal system is the subject of this rulemaking. We do not intend to treat the views expressed by NAS as necessarily dictating the outcome of this rulemaking, thereby foreclosing public scrutiny of important issues. For the reasons described below, we believe this proposed interpretation of the EnPA is consistent with the statute and prudent in that it avoids potential Constitutional issues. Further, this proposed interpretation supports an important EPA policy objective — ensuring an opportunity for public input upon all aspects of the issues presented in this rulemaking.

Section 801(a)(2) of the EnPA required a study by NAS that provides "findings and recommendations on reasonable standards for protection of the public health and safety." While this section of the EnPA calls for NAS to address three specific issues, Congress did not place any restrictions upon other issues NAS could address. The report of the Congressional conferees underscored that "the National Academy of Sciences would not be precluded from addressing additional questions or issues related to the appropriate standards for radiation protection at Yucca Mountain beyond those that are specified." (H.R. Rep. No. 1018, 102nd Cong., 2d Sess. 391 (1992)). Thus, given the potentially unlimited scope of the NAS inquiry under the statute, NAS could have provided findings and recommendations that would dictate literally all aspects of the public health and safety standards for Yucca Mountain, rendering our function a ministerial one.

Section 801(a)(1) of the EnPA plainly gave EPA the authority to issue, by rulemaking, public health and safety standards for Yucca Mountain. If at the same time that Congress gave NAS the authority to provide findings and recommendations on any issues related to the Yucca Mountain public health and safety standards, Congress also intended that NAS' findings and recommendations be binding upon us, then Congress would have effectively delegated to NAS a standard-setting authority that overrides our delegated rulemaking authority. Carried to its logical conclusion, under this view of the statute, NAS would have authority to establish the public health and safety standards, and to do so without a public rulemaking process. Then the direction for EPA to set standards "by rule" would be unnecessary or relatively meaningless. This tension in the statute can be reasonably resolved by interpreting the NAS' findings and recommendations as non-binding, but highly influential, expert guidance to inform our rulemaking.

Thus, we do not believe the statute forces our rulemaking to adopt mechanically the NAS' recommendations as standards. If it did, the statutory provisions would allow us to consider only those issues that NAS did not address. Further, the provisions calling for us to use standard rulemaking procedures in issuing the standards would be unnecessary to reach results that NAS already established.

The report of the conferees also indicates that Congress did not intend to limit our rulemaking discretion. The Conference Report provides that Congress intended NAS to provide "expert scientific guidance" on the issues involved in our rulemaking and that Congress did not intend for NAS to establish the specific standards:

> The Conferees do not intend for the National Academy of Sciences, in making its recommendations, to establish specific standards for protection of the public but rather to provide expert scientific guidance on the issues involved in establishing those standards. Under the provisions of section 801, the authority and responsibility to establish the standards, pursuant to rulemaking, would remain with the Administrator, as is the case under existing law. The provisions of section 801 are not intended to limit the Administrator's discretion in the exercise of his authority related to public health and safety issues. (H.R. Rep. No. 1018 at p. 391)

Our proposed interpretation of the EnPA as not limiting the issues for consideration in this rulemaking is consistent with the views we expressed to Congress during deliberations over the legislation. The Chairman of the Senate Subcommittee on Nuclear Regulation requested our views of the bill reported out of conference. The Deputy Administrator of EPA indicated that the NAS Report would provide helpful input. Moreover, EPA's Deputy Administrator pointed to the language, cited above, stating the intent of the conferees not to limit our rulemaking discretion and assured Congress that any standards for radioactive materials that we ultimately issue would be the subject of public comment and involvement and would fully protect human health and the environment. (138 Cong. Rec. S33,955 (daily ed. October 8, 1992)).

Our proposed interpretation also is consistent with the role that both NAS and Congress understood NAS would fulfill. During the Congressional deliberations over the legislation, NAS informed Congress that while it would conduct the study, it would not assume a standard-setting role because that is properly the responsibility of government officials. (138 Cong. Rec. S33,953 (October 8, 1992)).

Our proposed interpretation of the NAS Report also avoids implicating potentially significant Constitutional issues. Construing the EnPA as delegating to NAS the responsibility to determine the health and safety standards at Yucca Mountain may violate the Appointments Clause of the Constitution (Art. II, sec. 2, cl. 2), which imposes restrictions against giving Federal governmental authority to persons not appointed in compliance with that Clause. In addition, the Constitution places restrictions arising under the separation of powers doctrine upon the delegation of governmental authority to persons not part of the Federal government. We are not concluding, at this time, that an alternative interpretation would necessarily run afoul of Constitutional limits. However, we believe it is reasonable both to assume that Congress intended to avoid these issues when it adopted section 801 of the EnPA and to interpret the EnPA accordingly.

In summary, we do not believe we must, in this rulemaking, adopt all of the positions advanced by NAS. At the same time, the statute does give NAS a special role. As noted, the NAS' findings and recommendations have been the starting point for this rulemaking and our proposal is consonant with those findings and recommendations. In fact, the NAS Report influenced us heavily during the development of this proposed rule. We have included many of the findings and recommendations in whole in today's proposal, and we intend to continue to weigh the NAS Report heavily throughout the course of this rulemaking. We will tend to give greatest weight to the judgments of NAS about issues having a strong scientific component, the area where NAS has its greatest expertise. In addition, we will reach final determinations that are congruent with the NAS analysis whenever we can do so without departing from the Congressional delegation of authority to us to promulgate, by rule, public health and safety standards for protection of the public, which we believe requires the consideration of public comment and our own expertise and discretion.

We request public comment upon how we should view and weigh the NAS' findings and recommendations in this rulemaking. Public commenters should also address this issue in the context of the specific issues presented in this rulemaking. Commenters should indicate whether we have given proper consideration to the NAS' findings and recommendations, whether we should give them more or less weight, and what the resulting outcome should be.

The following sections describe our proposed public health and safety standards for Yucca Mountain and the considerations which underlie the set of standards we are proposing today. The next section addresses the storage portion of the proposed standards. All of the other sections pertain to the disposal portion of the standards.

<u>III.A. What is the Proposed Standard for Storage of the Waste? (proposed subpart A)</u>

Section 801(a)(1) of the EnPA calls for EPA's public health and safety standards to apply to radioactive materials "stored or disposed of in the repository at the Yucca Mountain site." (The repository is the mined portion of the facility constructed underground within the Yucca Mountain site. Hereafter, the term "repository" refers to the Yucca Mountain repository.) The EnPA differentiates between waste that is "stored" and waste that is "disposed," although it indicates that we must issue standards that apply to both types of activity. Congress was not clear regarding its intended use of the word "stored" in this context. Also, NAS did not address the issue of storage (see proposed §§ 197.02 and 197.12 for our proposed definitions of "storage" and "disposal"). The Yucca Mountain repository currently is conceived to be a disposal facility, not a storage facility, but that could change. Therefore, we propose to interpret this language as directing us to develop standards that apply to waste that DOE either stores or disposes of in the Yucca Mountain repository. The public health and safety standards we issue under section 801 of the EnPA would, therefore, apply to waste inside of the repository, whether it is there for storage or disposal.

The Department will also handle and might store radioactive material aboveground (that is, outside the repository). Those activities are covered by our previously promulgated standards for management and storage, codified at subpart A of 40 CFR part 191. The 40 CFR part 191 standards require that DOE manage and store SNF, HLW, and transuranic radioactive wastes at a site, such as Yucca Mountain, in a manner that provides a reasonable expectation that the annual dose equivalent to any member of the public in the general environment will not exceed 25 millirem (mrem) to the whole body. This is the standard which DOE must meet for WIPP and the greater confinement disposal (GCD) facility. (The GCD facility is a group of 120-feet deep boreholes located within the Nevada Test Site (NTS) which contains disposed transuranic wastes.)

The storage standards in 40 CFR 191.03(a) are stated in terms of an older dose-calculation method and are set at an annual whole-body-dose limit of 25 mrem/yr. The proposed storage standards for Yucca Mountain use a modern dose-calculation method known as "committed effective dose equivalent" (CEDE).[8] Even though today's proposal uses the modern method of dose calculation, we believe that the proposed dose level essentially maintains a similar

[8] The term "committed effective dose" in this rulemaking has the same meaning as the term "committed effective dose equivalent" which was used prior to the publication of ICRP Publication No. 60. It is used here since the term is less complicated and more compact. Also, the use of "committed effective dose" is consistent with subpart B of 40 CFR part 191 (58 FR 66398, 66402, December 20, 1993).

risk level as in 40 CFR 191.03(a) at the time of its promulgation (see the discussion of the different dose-calculation methods in the What should the Level of Protection Be? section later in this notice). The difference between these dose calculation procedures presents a problem in combining the doses for regulatory purposes. However, we have begun a rulemaking to amend both 40 CFR Parts 190 and 191. That rulemaking would update these limits to the CEDE methodology. We anticipate that we will finalize the amendments to parts 190 and 191 prior to the finalization of this rulemaking. If that does not occur, we would need to address the calculation of doses under the two methods in another fashion. For example, we could require that the doses occurring as a result of activities outside the repository be converted into annual CEDE for purposes of determining compliance with the storage standard. We request comments upon such an approach.

Section 801 of the EnPA specifically provides that the standards that we issue shall be the only "such standards" that apply at Yucca Mountain. Thus, the statute provides that the EnPA is the exclusive authority for "such standards" and, in turn, replaces our generally applicable standards for radiation protection to the extent that section 801 requires site-specific standards. Otherwise, our generic standards are not affected. As noted, we propose to interpret the scope of section 801 as applying to both storage and disposal of waste in the repository. Thus, waste inside the repository would be subject to the standards proposed in today's notice. Our generic standards in subpart A of 40 CFR part 191 will apply to waste outside of the repository.

Using this interpretation, we have considered the differences between the conditions covered by the storage standards in 40 CFR 191.03(a) and the conditions which could affect storage in the Yucca Mountain repository. The most significant difference is that the storage in

Yucca Mountain would be underground whereas most storage covered under 40 CFR part 191 is aboveground. Otherwise, the technical situations we anticipate under both the existing generic standards and the proposed Yucca Mountain standards are essentially the same. Also, one of our goals in issuing 40 CFR parts 190 and 191 was to bring the entire uranium fuel cycle under consistent EPA standards. Therefore, we are proposing that the part 197 standards continue the coverage of the uranium fuel cycle because SNF, a large part of the waste planned for emplacement in Yucca Mountain, is part of that fuel cycle. Therefore, we are proposing to extend a similar level of protection as in the 1985 version of subpart A of 40 CFR part 191. In other words, under the part 197 storage standards, exposures of members of the public from waste storage inside the repository would be combined with exposures occurring as a result of storage outside the repository but within the Yucca Mountain site. The total dose could be no greater than 150 microsieverts (µSv) (15 mrem) CEDE per year (CEDE/yr).

Our application of subpart A of 40 CFR part 191 to storage activities outside of the repository at the Yucca Mountain site is supported by the WIPP LWA. Section 8 of the WIPP LWA excludes Yucca Mountain from our generic disposal standards but not from the generic management and storage standards found in subpart A of 40 CFR part 191. If we finalize the proposed interpretation of section 801 of the EnPA as applying to radioactive material stored or disposed of in the repository, we would apply subpart A of 40 CFR part 191 to the storage activities outside of the repository at the site without further public notice.

We request comment upon our proposed interpretation that section 801 of the EnPA directs us to develop new standards that apply only to radioactive materials stored in the repository. We also request public comment upon whether we should instead construe section

801 of the EnPA as providing for the establishment of new storage standards, rather than applying the existing storage standards in 40 CFR part 191 to storage, or handling, of radioactive materials at the Yucca Mountain site prior to their movement into the repository. If we decide, based upon the alternative interpretation of section 801, to promulgate new storage standards for the site, we anticipate that we would adopt standards essentially the same as those in 40 CFR 191.03(a). Thus, we request public comment upon whether we should develop and adopt in this rulemaking, under section 801 of the EnPA, new standards for management and storage activities at the site, and request comments upon the adoption of such standards based upon those in 40 CFR 191.03(a).

III.B. What is the Standard for Protection of Individuals? (proposed §§ 197.20 and 197.25)

III.B.1. Should the Limit be on Dose or Risk?

Although a standard for limiting exposure of people to radiation can take many forms, NAS narrowed its final considerations to risk and dose, that is, a risk-based or dose-based standard. The numeric level of the proposed standard for protecting individual members of the public from radioactive materials disposed of in the Yucca Mountain disposal system is addressed in the What should the Level of Protection Be? section later in this notice. The discussion here explains why we selected a dose-based standard rather than a risk-based standard, as recommended by NAS.

Two forms of radiation exposure can occur depending upon the location of the source relative to the body — internal and external. Internal exposures occur when a person inhales or ingests contaminated air, food, water, or soil. External exposures occur because a person is near a radionuclide which is emitting X-rays, gamma rays, beta particles, or neutrons. “Dose” is a measure of the amount of radiation received by individuals resulting from exposure to radionuclides. “Risk” is the probability of an individual incurring an adverse health effect from exposure to radiation. The NAS defined “risk” as the product of two parameters: (1) the probability of an individual receiving a dose, and (2) the probability of incurring a health effect because of that dose (NAS Report p. 42). This rulemaking takes both of these factors into account. (The probability of an individual receiving a dose is part of the performance assessment and is discussed in the What are the Requirements for Performance Assessments and Determinations of Compliance? section later in this notice.) As mentioned in the previous section, these standards state radiation risk estimates as the probability of an individual developing a fatal cancer, since fatal cancers are the greatest harm to individuals from low-dose-rate radiation (NAS pp. 37-39).

Section 801(a)(1) of the EnPA directed that our standards for Yucca Mountain "shall prescribe the maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository...." At the same time, the EnPA calls for us to issue our standards "based upon and consistent with" the findings and recommendations of NAS. The NAS recommended that we adopt a standard expressed as risk rather than the dose standard that Congress prescribed. The NAS offered two reasons for its recommendation. First, a risk-based standard is advantageous relative to a dose-based standard because it "would not have to be revised in subsequent rulemakings if advances in scientific knowledge reveal that the dose-response relationship is different from that envisaged today" (NAS Report p. 64). Second, a standard in the form of risk more readily enables the public to comprehend and compare the standard with human-health risks from other sources.

We have reviewed and evaluated the merits of a risk-based standard as recommended by NAS. However, we are proposing a dose-based standard for the following reasons. First, both national and international radiation protection guidelines developed by bodies of non-governmental radiation experts, such as ICRP and NCRP, generally have recommended that radiation standards be established in terms of dose. Also, national and international radiation standards, including the individual-protection requirements in 40 CFR part 191, are established almost solely in terms of dose or concentration, not risk. Therefore, a risk-based standard will not allow a convenient comparison with the numerous existing radiation guidelines and standards that are stated in terms of dose.

Second, we have an established methodology for calculating dose that is described in Federal Guidance Reports Nos. 11 and 12 (Federal Guidance). The development of this methodology was a combined effort of many Federal agencies involved in radiation protection and has become Federal policy. The guidance provides a consistent methodology for calculating doses for regulatory purposes. By contrast, there is currently no Federal Guidance Report, in final form, for calculating risk from radiation exposure.

Third, we have based the proposed dose-based standard upon the risk of developing a fatal cancer as a result of that level of exposure based upon a linear, non-threshold, dose-response relationship. We would establish a risk-based standard in the same manner. Thus, a risk-based standard, like a dose-based standard, depends upon current knowledge and assumptions about the chance of developing fatal cancer from a particular exposure level. Dose and risk are closely related; one can be converted to the other simply by using the appropriate factor. Therefore, both dose- and risk-based standards are based upon scientific assumptions that could change and no matter how it is expressed, the standard is based upon risk.

Finally, section 801(a)(1) of the EnPA specifically calls for a dose-based standard. Most commenters supported this by asking for a dose-based standard rather than a risk-based standard.

Accordingly, we are proposing a standard expressed as a limit on dose. We are requesting comments upon the proposed form of the standard, including whether the standard should be expressed as risk.

III.B.2. What should the Level of Protection Be?

As noted previously, section 801(a)(1) of the EnPA calls for our Yucca Mountain standards to "prescribe the maximum annual effective dose equivalent to individual members of the public from releases of radioactive materials." Development of the individual-protection standard requires us to evaluate and specify several factors. These factors include the level of protection, who the standards should protect, and how long the standards should provide protection. Determining the appropriate dose level is ultimately a question of both science and public policy. The NAS stated in its Report: "The level of protection established by a standard is a statement of the level of the risk that is acceptable to society. Whether posed as ‘How safe is safe enough?’ or as ‘What is an acceptable level?’, the question is not solvable by science” (NAS Report p. 49). We seek to find answers to these questions for the Yucca Mountain disposal system through this rulemaking.

We considered the NAS findings and recommendations in our determination of the CEDE level that would be adequately protective of human health. We also reviewed established EPA standards and guidance, other Federal agencies’ actions for both radiation and non-radiation-related actions, and other countries' regulations. In addition, we evaluated guidance on dose limits provided by National and international, non-governmental, advisory groups of radiation experts.

The NAS recommended a range of risk levels that we could use as a reasonable starting point in this rulemaking (NAS Report p. 5). The range of annual risk of fatal cancer suggested by NAS was 1 chance in 100,000 (1×10^{-5}) to 1 chance in 1,000,000 (1×10^{-6}) (this corresponds to a range of 20 to 2 mrem CEDE/yr). The NAS based its recommendation upon its review and evaluation of our actions, other Federal actions, guidelines developed by National and international groups, and regulations of other countries. For these standards, we are proposing a limit of 150 µSv (15 mrem) CEDE/yr. This limit corresponds approximately to an annual risk of 7 chances in 1,000,000 (7×10^{-6}) — within the range that NAS recommended as a starting point for consideration.

Table 1 below lists the dose limits of other current EPA and NRC regulations (adapted from NAS Report p. 50). Today's proposed standard of 150 µSv (15 mrem) CEDE/yr is within the range of these established standards. Further, it is consistent with the individual-protection standard at 40 CFR 191.15 in our generic disposal standards which limits the annual CEDE to 150 µSv (15 mrem)/yr.

TABLE 1.—CURRENT EPA AND NRC DOSE LIMITS ON VARIOUS ENVIRONMENTAL CONCERNS

Environmental Concern	Limit*
Low-Level Waste (10 CFR part 61)	250 µSv (25 mrem)/yr
License Termination (10 CFR part 20)	25 mrem TEDE**/yr
Uranium Fuel Cycle (40 CFR part 190)	25 mrem/yr
Generic Standard for Management and Storage of SNF and HLW (40 CFR 191.03)	25 mrem/yr
Generic Individual-Dose Standard for Disposal of SNF and HLW (40 CFR 191.15)	150 µSv (15 mrem) CEDE/yr
National Emission Standards for Hazardous Air Pollutants (40 CFR part 61, subparts H and I)	10 mrem CEDE/yr
SNF and HLW Disposal Limit for Underground Sources of Drinking Water (40 CFR 191.24)	4 mrem/yr for man-made beta- and photon-emitting radionuclides

*Unless otherwise noted, only whole-body dose limits are listed; there may also be other requirements for any particular environmental concern. The 25-mrem/yr, whole-body-dose limit established in 1985 is essentially equivalent to the risk associated with today's dose rate of 150 µSv (15 mrem) CEDE/yr (58 FR 66402, December 20, 1993).
**TEDE (total effective dose equivalent) is NRC's term for CEDE. This regulation was not included in the NAS Report.

We note that, except for 40 CFR 191.15, 40 CFR part 61, and 10 CFR part 20, the dose limits in Table 1 are stated in terms of an old dose system. For example, the annual limits in 40 CFR 191.03(a) are 25 mrem for the whole body, 75 mrem for the thyroid, or 25 mrem for any other organ (only the whole-body limit is listed in Table 1). We established these dose levels in 1985 (50 FR 38085, September 19, 1985) under a different system for calculating doses than the more recent rulemakings that use the CEDE concept. We estimate that the 25-mrem/yr, whole-body-dose limit established in 1985 is essentially equivalent to the risk associated with today's proposed limit of 150 µSv (15 mrem) CEDE/yr (58 FR 66398, 66402, December 20, 1993).

In addition, the proposed 150-µSv (15 mrem)-CEDE/yr limit in today's proposal is consistent with other current standards. For example, our limits on radiation exposure through the air is part of the set of limits for pollutant releases known as the National Emission Standards for Hazardous Air Pollutants (NESHAPs, 40 CFR part 61). Since our NESHAPs limit of 10 mrem/yr covers radionuclide releases into only the air, the 150 µSv (15 mrem) CEDE/yr standard being proposed for 40 CFR part 197 is consistent with the NESHAPs limit because it applies to all potential pathways, that is, the dose limit is higher but includes other pathways in the analysis.

In summary, based upon our review of the guidance, regulations, and standards cited above, and the NAS Report, we are proposing a standard of 150 µSv (15 mrem) CEDE/yr for the Yucca Mountain disposal system. We request comment upon the reasonableness of this level of protection.

III.B.3. What Factors can lead to Radiation Exposure?

Protection of the public from exposure to radioactive pollutants requires knowledge and understanding of three factors: the source of the radiation, the pathways leading to exposure, and the recipients of the radiation. This section provides a discussion of the source of radiation and pathways of exposure. The following two sections discuss the recipients of the dose. The development of standards to protect public health and safety from radionuclides released from waste disposed of in the Yucca Mountain disposal system must include consideration of the sources of radiation and pathways which could lead to exposure of humans. The mechanisms of exposure are the basis of an analysis called the performance assessment. The performance assessment is the quantitative analysis of the projected behavior of the disposal system.

Source. The waste disposed of in Yucca Mountain will contain many different radionuclides including unconsumed uranium, fission products (for example, cesium-137 and strontium-90), and transuranic elements (for example, plutonium and americium).

The inventory of radionuclides over time will depend upon the type and amount of radionuclides originally disposed of in the disposal system, the half-lives of the radionuclides, and the amount of any radionuclides formed from the decay of parent radionuclides (see the BID). In the time frame of tens- to hundreds-of-thousands of years, most radionuclides initially present in SNF and HLW will decay to essentially no radioactivity. Therefore, the waste will eventually have radiologic characteristics similar to a large uranium ore body (see the BID).

To delay the movement of radionuclides into the biosphere, DOE plans to use multiple barriers. These barriers would be man-made (engineered) and natural based upon the design of, and conditions in and around, the disposal system.

Engineered barriers must be designed to delay release of radionuclides from the repository. For example, an engineered barrier could be the waste form. The Department plans to convert liquid HLW derived from reprocessing of SNF into a solid by entraining the radionuclides into a matrix of borosilicate glass; NRC will likely consider this an engineered barrier. The molten glass then would be poured into and hardened in a second man-made barrier, a metal container (see the BID). In addition, it is possible to have other man-made barriers in the repository to serve as part of the disposal system (see the BID).

Natural barriers at Yucca Mountain also could slow the movement of radionuclides into the accessible environment. For instance, the Department plans to construct the repository in a layer of tuff located above the water table. The relative dryness of the tuff around the repository would limit the amount of water which comes into contact with the waste. It also would retard the future movement of radionuclides from the waste into the underlying aquifer. Any radioactive material that dissolved into infiltrating water, originating as surface precipitation, still would have to be moved to the saturated zone. Minerals, such as zeolites, contained within the tuff beneath the repository could act as molecular filters and ion-exchange agents for some of the released radionuclides, thereby slowing their movement. Such minerals also could limit the amount of water that contacts the waste and could help retard the movement of radionuclides from the waste to the water table. This mechanism would be most effective if flow was predominantly through the pores in the rock, also know as the matrix (see the BID).

Pathways. Once radionuclides have left the waste packages, they could be carried by water or air and reach the public. Upon release from the waste packages, most radionuclides will be carried by ground water away from the repository. However, those in a gaseous form, such as carbon-14 (^{14}C) in the form of carbon dioxide, will be carried by air moving through the mountain.

Movement via water. Radionuclides will not be moved into the water table instantaneously. The length of time it takes depends partly upon how much the water moves via fractures or through the matrix of the rock. Once radionuclides reach the saturated zone, they would move away from the disposal system in the direction of ground water flow.

There are currently no perennial rivers or lakes adjacent to Yucca Mountain to further transport contaminants. Therefore, based upon current knowledge and conditions, ground water and its usage will likely be the main pathway leading to exposure of humans. Current knowledge suggests that the two major ways that people would use the contaminated ground water are: (1) drinking and domestic uses; and (2) agricultural uses (see the BID). In other words, radionuclides that reach the public could deliver a dose if an individual: (1) drinks contaminated ground water or uses it directly for other household uses; (2) drinks other liquids containing contaminated water; (3) eats food products processed using contaminated water; (4) eats vegetables or meat raised using contaminated water, or (5) is otherwise exposed as a result of immersion in contaminated water or air or inhalation of wind-driven particulates left following the evaporation of the water.

Movement via air. Some radionuclides could be carried by moving air. The largest known source of potential movement by air in Yucca Mountain is carbon dioxide containing ^{14}C. Airborne radionuclides might move through the tuff overlying the repository and exit into the atmosphere following release from the waste package. Once the radioactive gas enters the atmosphere, it would disperse. This dispersion would probably be global and, therefore, become greatly diluted. The major pathway for exposure of people by ^{14}C is the uptake of radioactive carbon dioxide by plants that humans subsequently eat (see the BID).

III.B.4. Who will be Representative of the Exposed Population?

To determine whether the Yucca Mountain disposal system complies with the standard, it will be necessary for DOE to calculate the dose to some individual or group of individuals exposed to releases from the repository and compare the calculated dose with the limit established in the standard. The standard must specify, therefore, the individual or group of individuals for whom the dose calculation is to be made.

The NAS definition of critical group. The NAS Report recommended that we base the standards for protection of individuals upon risk incurred by a critical group (CG). The CG would be the group of people which, based upon cautious, but reasonable, assumptions, has the highest risk of incurring health effects due to releases from the disposal system. The ICRP introduced the concept of a CG in order to account for the variation of dose which may occur in a population due to differences in age, size, metabolism, habits, and environment. In other words, the ICRP recommends the use of a group of people because individuals might have personal traits which make them much more or less vulnerable to releases of radiation than the average within a small group of the most highly exposed individuals. The ICRP defines the CG as a relatively homogeneous group of people whose location and habits are such that they represent those individuals expected to receive the highest doses as a result of the discharge of radionuclides. The NAS adapted the CG concept to a risk framework for the development of an individual-risk standard and recommended the following description of the CG (NAS Report p. 53):

The critical group for risk should be representative of those individuals in the population who, based on cautious, but reasonable, assumptions, have the highest risk resulting from repository releases. The group should be small enough to be relatively homogeneous with respect to diet and other aspects of behavior that affect risks. The critical group includes the individuals at maximum risk and is homogeneous with respect to risk. A group can be considered homogeneous if the distribution of individual risk within the group lies within a total range of a factor of ten and the ratio of the mean of individual risks in the group to the standard is less than or equal to one-tenth. If the ratio of the mean group risk to the standard is greater than or equal to one, the range of risk within the group must be within a factor of 3 for the group to be considered homogeneous. For groups with ratios of mean group risk to the standard between one-tenth and one, homogeneity requires a range of risk interpolated between these limits.

The NAS also recommended that the CG risk calculated for purposes of comparison with the risk limit established in the standard is the average of the risks of all the members in the group. Using the average risk avoids the problem of the outcome being unduly influenced by unusual habits of individuals within the group.

The NAS indicated that in order to select a CG, the person or persons likely to be at highest risk from among the larger, exposed population must be specified. To accomplish this, one must make assumptions about the nature of human activities, lifestyles, and pathways that affect the level of exposure. The set of circumstances that affects the dose received, such as where people live, what they eat and drink, and other lifestyle characteristics, is a very important part of the exposure scenario. Many human behavior factors important to assessing repository performance vary over periods that are short in comparison with the compliance period proposed for these standards. The past several centuries have seen radical changes in human technology and behavior, many of which were not reasonably predictable. Given this potential for rapid change, we believe that it is not possible to know what patterns of human activity and changes in human biology might occur thousands of years from now. For the purpose of compliance with the standard, therefore, we are proposing that it is appropriate to use many of the current characteristics of members of the public in the vicinity of Yucca Mountain in the compliance assessments required by these standards (see the <u>What should be assumed about the Future Biosphere?</u> section later in this notice).

The NAS Report presented two illustrative approaches for formulating an exposure scenario for determining compliance. The NAS also clearly stated that there might be other methods to reach the same objective (NAS Report p. 100). One approach, described in Appendix C of the NAS Report, <u>A Probabilistic Critical Group</u>, used statistical methods and probabilities to characterize a CG. The second, <u>The Subsistence-Farmer Critical Group</u>, described in Appendix D, identified a subsistence farmer as a principal representative of the CG.

<u>The NAS probabilistic critical group.</u> Appendix C of the NAS Report described a "probabilistic critical group." This section describes the contents of Appendix C of the NAS Report.

The NAS probabilistic CG approach would require use of a theoretical population distribution which we would, or require DOE to, develop by using a mathematical method known as “Monte Carlo.” The Monte Carlo method is a mechanism to randomly select values of parameters which have a range of possible values. The parameters would be present-day environmental parameters, including soil quality, land slope, growing season, depth to the aquifer, and population distribution and lifestyles. The individuals who comprise the CG may represent a variety of economic lifestyles and activities. The analysis would then use the variability of those parameters in the region around Yucca Mountain to arrive at the theoretical population for the calculation of radiation exposure. This theoretical population would then, according to NAS, be combined with Monte Carlo simulations of the distribution of contaminated ground water in time and space (NAS Report p. 148). According to NAS, each simulation would generate a plume path which could be overlain on a map of potential farm density or water use to determine a potential exposure area. Each of these potential plume paths is known as a “realization.” Values for parameters, including well depths, rates of water use, food sources, and consumption rates, are determined by sampling from the parameter-value distributions. For each plume realization of the contamination in the aquifer, the results of the exposure simulations are combined to give a spatial distribution of maximum exposures for the locations likely to be inhabited. This approach would use a large number of simulations of plume realizations to identify critical subgroups with the highest risk. It would then be used to calculate the arithmetic average of the risk of all critical subgroups over all plume realizations to estimate the risk for the CG. In determining compliance, the Commission would compare this estimate with the risk limit in the standard.

We considered proposing the probabilistic CG approach but are not doing so for the following reasons. First, there is no relevant experience in applying the probabilistic CG approach. Second, the approach is very complex and difficult to implement in a manner that assures it would meet the requirements of defining a CG. Third, we are concerned that this approach does not appear to identify clearly who is being protected. Finally, a significant majority of the comments that we have received upon the NAS Report opposes the probabilistic CG approach.

The NAS subsistence-farmer critical group. The approach in Appendix D of the NAS Report specified one or more subsistence farmers as the CG. It made assumptions designed to define the farmer at maximum risk to be included in the CG. This section describes the contents of Appendix D of the NAS Report.

The subsistence-farmer CG is a definable, highly exposed segment of the larger, exposed population. The subsistence farmer would be assumed to: (1) be a person with eating habits and response to doses of radiation that would be average for present-day people and (2) obtain all potable water and grow all of his or her own food using water withdrawn from the aquifer contaminated with radionuclides from the disposal system. The water used by this CG would be withdrawn at a location downgradient from and outside the footprint of the repository at the point of maximum potential concentration of ground water contamination, provided that no natural geologic features preclude drilling for water at that location. (The footprint of the repository is the circumscription of the outermost, original emplacement locations of the waste.)

Concentrations of radionuclides in the extracted ground water may be smaller than in undisturbed ground water due to pumping; this possibility could be used when evaluating exposures (NAS Report p. 155). As a result of uncertainty, there will be probabilistic distributions of radionuclide concentrations, as they vary in time and space in the aquifer outside the repository footprint, which are the input variables needed to estimate the risk. The radionuclide distributions in the aquifers, in turn, depend upon the performance of the components of the natural and engineered barrier systems. Projections of their performance also contain uncertainty and likely will be subject to probabilistic assessment. Any assessment of the potential doses from the repository, therefore, must consider the probability of processes and events that influence eventual concentrations of radionuclides in aquifers supplying water to the CG.

Overall, the “expected” risk for the average member of this CG would be about one-half that of the most-exposed subsistence farmer (NAS Report p. 158). This average risk to the members of the CG would be compared with the standard selected for compliance.

We considered proposing that the protected individual(s) be the subsistence-farmer CG. The CG concept has been utilized within the U.S. in various ways. The NRC uses the CG concept in assessing compliance with NRC standards for radionuclide releases from nuclear facilities. For example, the Commission uses the CG concept in: (1) licensing actions involving dose calculations under 10 CFR part 40, appendix A; (2) its radiological criteria for license termination of all NRC-licensed facilities at 10 CFR part 20, subpart E; and (3) its draft guidance for LLW disposal under 10 CFR part 61. The State of Washington recently implemented the CG concept in actions relating to U.S. Ecology’s LLW site at Hanford, and the State of Texas endorses CG in its decommissioning standards. Also, a great deal of international guidance exists that discusses the use of CG. The ICRP endorses CG, and has recommended the CG concept in numerous documents, both recent and dating back as far as 1977. Canada, Sweden, Switzerland, and the United Kingdom are among those individual nations that have adopted the CG methodology for radioactive waste storage and disposal.

We prefer an approach to exposure assessment that is consistent with other Agency programs (<u>Guidance on Risk Characterization for Risk Managers and Risk Assessors</u>, Deputy

Administrator F. Henry Habicht II, February 26, 1992) and which we believe provides a level of protection substantially equivalent to that which would be achieved by the CG concept.

Our proposal for the protection of individuals. Most of our programs use an approach for the development of exposure scenarios that involves determining the high-end range of doses or exposures. Conceptually, this range is that above the 90th percentile of the entire (either measured or estimated) distribution of potential doses within the exposed population. Conversely, the NESHAPs program for radionuclides and the individual-protection requirements in the generic SNF and HLW disposal standards at 40 CFR 191.15 require calculation of the individual dose for a person assumed to reside at a location where that person would receive the highest dose. However, other Agency programs use a different approach to protect individuals by using "reasonable, maximum exposure" (RME) conditions. The National Contingency Plan describes an approach to be used for the RME scenario to protect individuals as "a product of factors, such as concentration and exposure frequency and duration, that are an appropriate mix of values that reflect averages and 95th percentile distributions" (55 FR 8666, 8710, March 8, 1990). In the past, we have defined "reasonable maximum" to mean potential exposures that are likely to occur. The method for calculating the RME is to estimate the high-end range of possible exposures by identifying the factors which have the greatest effect upon the size of the dose, and using maximum or nearly maximum values for one or a few of these factors, leaving the others at their average values (57 FR 22888, 22922, May 29, 1992). In this approach, we select a hypothetical individual who would be representative of the most highly exposed individuals. We call this individual the reasonably maximally exposed individual (RMEI). To be effective, the RMEI approach must avoid incompatible combinations of parameter values, such as, low body weight used in combination with high intakes.

Thus, we intend for this procedure to project doses that are within a reasonably expected range rather than projecting the most extreme case. However, the procedure is also meant to identify an individual dose which is well above the average dose in the exposed population. The ultimate goal and purpose is to estimate a level of exposure that is protective of the vast majority of individuals at a site, but is still within a reasonable range of potential exposures.

For the preceding reasons, we are proposing the RMEI concept as our preferred approach instead of the CG approach. The United States and other countries have used the concept of a hypothetical individual to represent future populations in radioactive-waste management programs. This is consistent with widespread practice, current and historical, of estimating dose and risk to highly exposed individuals even when the exposure habits of future people cannot be specified or accurately calculated, as in this case where doses must be projected for very long periods. The approach is straightforward and relatively simple to understand. We believe that this approach provides protection similar to that afforded by the NAS recommendation to use a CG. The RMEI model uses a series of assumptions about the lifestyle of a hypothetical individual. The desired degree of conservatism can be built into the model through choices of assumed values of RME parameters. However, these values would be within certain limits since we are proposing to require the use of Yucca Mountain-specific characteristics in choosing those parameters and their values. In subpart B of 40 CFR part 197, we propose a framework of assumptions for NRC to incorporate into its implementing regulations.

Our proposed RMEI would be representative of a future population group termed "rural-residential." The CEDE received by this RMEI would be calculated by DOE using cautious, but reasonable, exposure parameters and parameter-value ranges. The projected CEDE would be used by NRC in the determination of compliance with the proposed standards. We believe that the results obtained by using this approach would be similar to those which would be obtained by using the subsistence-farmer CG approach put forth in Appendix D of the NAS Report. In both cases, the objective is to determine the magnitude of the potential exposure using reasonable, not extreme, assumptions. Under the proposed standards, the RMEI will have food and water intake rates, diet, and physiology like that of individuals currently living in the downgradient direction of flow of the ground water passing under Yucca Mountain. The Department will perform the dose calculation to estimate exposure resulting from releases from the waste into the accessible environment based upon the assumption of present-day conditions in the vicinity of Yucca Mountain. Presently, we expect the ground water pathway to be the most significant pathway for exposure from radionuclides that are transported from the repository. Our initial evaluation of potential exposure pathways from the disposal system to the RMEI suggests that the dominant fraction of the dose incurred by the RMEI likely will be from ingestion of food irrigated with contaminated water (see the BID). It is possible, however, that another exposure pathway will be determined by DOE and NRC to be more significant for radiation exposure. Consequently, DOE and NRC must consider and evaluate all potentially significant exposure pathways in the performance assessment. As a result of the performance assessment, there will be a distribution of the highest potential doses incurred by the RMEI. We are proposing that the mean or median value (whichever is higher) of that distribution be used by NRC to determine compliance with the individual-protection standard. We request comments upon this method of determining compliance with the individual-protection standard.

We are also requesting comments upon the alternative of adopting the CG approach rather than the RMEI. Comments supporting the CG approach should address the level of detail EPA's rule should include on the parameters of the CG.

Exposure scenario for the RMEI. A major part of the exposure scenario is the location of the RMEI. In preparing to propose a location for the RMEI, we collected and evaluated information on the natural geologic and hydrologic features, such as topography, geologic structure, aquifer depth, aquifer quality, and the quantity of ground water, that may preclude drilling for water at a specific location. Based upon these factors and the current understanding of ground water flow in the area of Yucca Mountain, it appears that an individual could reside anywhere along the projected radionuclide flow path extending from Forty-Mile Wash, approximately five kilometers (km) from the proposed repository location, to the southwestern part of the Town of Amargosa Valley, Nevada, where the ground water is close to the land surface and where most of the farming in the area is done. However, an individual's ability to reside at any particular point along that path depends upon that individual's purpose and available resources. To explore these variations, we developed the four scenarios described below. We present our evaluation of factors associated with these scenarios more fully in the BID. We welcome comment upon the appropriateness of each of these scenarios and upon our preferred scenario. In developing scenarios, we assumed that the level of technology and economic considerations affecting population distributions and life styles in the future are the same as today (for more detail, see the What should be assumed about the Future Biosphere? section below).

The RMEI in the first scenario is a subsistence (low technology) farmer. Such an individual would have continuous exposure to radionuclides in water, air, and soil which are arriving through all exposure pathways. The RMEI's location and habits would be generally consistent with historical locations of Native Americans and early settlements in Amargosa Valley and influenced heavily by easy access to water, that is, where the water table is near the surface (approximately 30 - 40 km away from the disposal system). In addition, all of the RMEI's water and food would come from contaminated sources. We did not choose this option because we believe that such a scenario is overly conservative given the site-specific characteristics of the area and reasonable consideration of the lifestyles of individuals in that area.

In the second scenario, we considered using a commercial farmer as the RMEI. We evaluated economic factors and current and potential future technologies which could be economically viable. There are areas in the vicinity of Yucca Mountain which are currently being farmed commercially or could be economically farmed based upon reasonable assumptions, current technology, and experience in other arid parts of the western United States. The exposure pathways in this scenario would be the same as those used for the subsistence-farmer scenario. We did not choose this as our preferred scenario since we believe that commercial farming would not be representative of the general population and would not be likely in areas other than where there is currently such farming, approximately 30 kilometers from the disposal system.

The third scenario, selected as our preferred approach, involves a rural-residential RMEI. We assume that the rural-residential RMEI is exposed through the same general pathways as the subsistence farmer. However, this RMEI would not be a full-time farmer but would do personal gardening and earn income from other sources of work in the area. We assume further that all of the drinking water (two liters per day) and some of the food consumed by the RMEI is from the local area. The consumption of two liters per day of drinking water is a high value since people consume water from outside sources, such as commercial products. Similarly, we assume that local food production will use radioactively contaminated water coming from the disposal system. We believe this lifestyle is similar to that of most people living in Amargosa Valley today.

The fourth scenario which we considered is domestic use of an underground source of drinking water (USDW) by a community living near the repository site. A USDW is essentially an aquifer which is large enough to supply or could supply a public water system (the full definition is in 40 CFR 144.3). Based upon current water usage in the arid western United States, a public water supply inside of the current NTS could exist since a community would have greater resources to access and recover water than would most individuals. Such a community water supply would have characteristics similar to DOE's water wells J-12 and J-13. These wells have supplied water needs (including human consumption) since the early 1960s for the Federal government. While we consider such a scenario possible, it could be less protective than the rural-residential scenario because it would not protect individuals from the ingestion of contaminated home-grown food. Also, we consider this scenario less representative of current conditions for most people in the vicinity of Yucca Mountain.

Location of the RMEI. The location of the RMEI is a basic part of the exposure scenario. We considered locations within a region occupying an area bordering Forty-Mile Wash, within a few kilometers of the repository site, to the southwestern border of the Town of Amargosa Valley. This region, which we believe is hydrologically downgradient from Yucca Mountain, can be considered as three general subareas.

The first subarea occupies the land south from near Yucca Mountain to the vicinity of U.S. Route 95. This subarea has deep ground water (up to about 300 meters) which is accessed by Federally owned wells used for DOE activities associated with Yucca Mountain and the NTS. This land is currently under government control and ownership. In addition, the likelihood of small or economically viable agricultural activities in this area is questionable when the depth to the water table is taken into consideration.

The next subarea borders the first and extends several kilometers south of U.S. Route 95. The northern portion of the Town of Amargosa Valley, including the businesses at the intersection of U.S. Route 95 and Nevada State Route 373 (Lathrop Wells), is included in this subarea. This subarea currently includes about 15 residents and no agricultural activities, although abandoned irrigation wells exist (see the BID). The depth to water in this area ranges from slightly more than 100 to about 60 meters. The U.S. Natural Resource Conservation Service has designated the types of soils in this area as suitable for rangeland and wildlife habitat.

The third subarea borders the second and covers the remainder of the Town of Amargosa Valley. This subarea is the closest downgradient location to Yucca Mountain with perennial agricultural activity. The depth to ground water is relatively shallow — approximately 50 to 15 meters. The agriculture consists of both personal gardens and commercial activities. The commercial agriculture is a mainstay of the local economy. Commercial farms produce crops, livestock, and dairy products for either local consumption or for transport out of the region. Most of the residents of the Town of Amargosa Valley are within this subarea, as are the community center, school, clinic, library, post office, and sheriff's office. The population consists of all age groups.

Based upon these considerations of the subareas, we propose that the intersection of U.S. Route 95 and Nevada State Route 373, known as Lathrop Wells, is a likely location for the

RMEI. In this example, we do not consider it probable that the rural-residential RMEI would occupy locations significantly north of U.S. Route 95. We make this assumption mainly because the rough terrain and increasing depth to ground water nearer to Yucca Mountain would likely discourage settlement by individuals because access to water is more difficult than it would be a few kilometers farther south. Also, there are currently several residents and businesses near this location whose source of water is the underlying aquifer (which we understand flows from under Yucca Mountain). Therefore, we believe that it is reasonable to assume that individuals could reside near this intersection in the future.

Farming occurs today farther south, in the southwestern portion of the Town of Amargosa Valley in an area near the California border and west of Nevada State Route 373. However, soil conditions in the vicinity of Lathrop Wells are similar to those in southwestern Amargosa Valley. Therefore, it should be feasible for the RMEI to grow some of his or her own food, including a grazing cow, using a fraction of the water recovered but not used for household purposes. Larger-scale food production at Lathrop Wells is unlikely because of the cost of recovering sufficient water. To supplement the gardening and grazing, we propose that it is also reasonable to assume that the RMEI would obtain much of his or her food from the local area.

Finally, we believe that a rural-residential RMEI near Lathrop Wells would be among the most highly exposed individuals in the downgradient direction from Yucca Mountain. We believe that this is true even though individuals residing closer to the repository (where the ground water is at a greater depth) could be consuming higher concentrations of radionuclides in their drinking water. Because of the significant cost of finding and withdrawing the ground water, we further believe that individuals living nearer the repository are unlikely to withdraw water from the significantly greater depth and in the much larger quantities needed for farming activities. Based upon our analyses of potential pathways of exposure, discussed above, we believe that irrigation would be the most likely pathway for most of the dose from the most soluble, least retarded radionuclides (such as technetium-99 and iodine-129). The percentage of the dose that results from irrigation would depend upon the assumptions about the fraction of all food assumed to be consumed by the RMEI from gardening or other crops grown using contaminated water. We also are proposing that protection of a rural-residential RMEI would be protective of the general population (see the <u>How will the General Population be Protected?</u> section below).

Our identification of Lathrop Wells as a potential location of the RMEI is based upon a review of available, site-specific information. Of course, DOE and NRC must consider other, more appropriate locations based upon additional data which DOE or others may developed later, but the selection of that other location must be based upon the same considerations used for this example. For example, if DOE subsequently determines that the direction of ground water flow is different than we have assumed, DOE and NRC must choose the location, at the same distance from the center of the repository footprint as the original point of compliance, where the highest radionuclide concentrations occur.

As stated earlier, the method of calculating the RME is to select average values for most parameters except one or a few which are set at their maximum, that is, high-end, values. We believe that the Lathrop Wells location and a consumption rate of two liters per day of drinking water from the plume of contamination represent high-end values for two of these factors. The Commission may identify additional parameters for which to assign high-end values in projecting the dose to the RMEI. To the extent possible, NRC should use site-specific information for any remaining factors. For example, NRC should use the most accurate projections of the amount of contaminated food that would be ingested in the future. Projections might be based upon surveys which indicate the percentage of the total diet of Amargosa Valley residents which is from food grown in the Amargosa Valley area.

We particularly request comment upon whether:

(1) based upon the above criteria, there is now sufficient information for us to adequately support a choice for the RMEI location in the final rule or should we leave that determination to NRC in their licensing process based upon our criteria;

(2) another location in one of the three subareas identified previously should be the location of the RMEI; and

(3) Lathrop Wells and an ingestion rate of two liters per day of drinking water are appropriate high-end values for parameters to be used to project the RME.

We also request comment upon the potential approaches and assumptions for the exposure scenario to be used for calculating the dose incurred by the RMEI.

III.B.5. How will the General Population be Protected?

In section 801(a)(2)(A) of the EnPA, Congress asked whether an individual-protection standard could also protect the general population. In response, the NAS concluded that an individual-protection standard could provide such protection for the case of the proposed Yucca Mountain repository. The NAS premised this conclusion upon the condition that the public and policymakers would accept the idea that extremely small individual radiation doses spread out over large populations pose a risk that is negligible (NAS Report p. 57). The NAS refers to this concept as “negligible incremental risk” (NAS Report p. 59). Earlier, we described our proposed individual-protection standard for the RMEI which would establish the highest allowable radiation dose. This section of the notice raises another question — should we also adopt a standard to limit the possible widespread exposure of whole populations to extremely small individual doses?

In discussing the feasibility of protecting the general population from releases of radionuclides from Yucca Mountain, NAS considered the potential for the release of gaseous radionuclides. The NAS Report explained how the release of carbon dioxide gas containing ^{14}C from the Yucca Mountain disposal system might expose a large population:

> Global populations might be affected because radionuclide releases from a repository can in theory be diffused throughout a very large and dispersed population. In the case of Yucca Mountain, the likely pathway leading to widely dispersed radionuclides is via the atmosphere beginning with release of carbon dioxide gas containing the carbon-14 (^{14}C) radioactive isotope which might escape from the waste canisters. (NAS Report p. 7)

On page 61 of its Report, NAS estimated that the average dose to members of the global population, based upon this scenario, to be 0.003 μSv/year (0.0003 mrem/yr) and equated that to an annual risk of fatal cancer of 1.5 in 10 billion (1.5×10^{-10}).

The NAS relied upon the recommendations of the NCRP in its report titled "Limitation of Exposure to Ionizing Radiation" (NCRP Report No. 116) to support their claim that such doses are negligibly small. In this report, the NCRP stated that a radiation dose of less than 10 μSv (1 mrem)/yr for any source or practice would represent a "negligible incremental dose." The NCRP endorsed the assumption that there is some radiation risk for every radiation exposure. Further, they explained that there are great uncertainties in trying to understand the meaning of radiation effects upon populations, especially when these effects are calculated by summing extremely small individual doses among huge populations. Agreeing with this concept, the NAS preferred to use risk instead of dose. The NAS then estimated the risk level associated with the NCRP's NID level of 10 µSv/yr and adopted the term "negligible incremental risk." The NAS then proposed this NIR level as the starting point for a process to establish a risk level for individuals that would be "negligible."

For different reasons, we provisionally agree with the NAS that an individual-risk standard can adequately protect the general population near Yucca Mountain. Our agreement is based upon the particular characteristics of the Yucca Mountain site. We emphasize that our view relates to the specific circumstances associated only with Yucca Mountain. We are not proposing to adopt either an NID or NIR level. We are concerned that such an approach is not appropriate in all circumstances. Again, our proposed determination that an individual-risk standard is adequate to protect both the local and general population is based upon considerations unique to the Yucca Mountain site – it is not a general policy judgment by us upon other uses of the concept of NID or NIR.

We considered the NAS suggestion to adopt a general NIR level but have not done so because of reservations regarding the reasoning and analysis employed by NAS. As noted above, NAS referred to the NID level of 10 µSv (1 mrem)/yr per source or practice recommended by the NCRP. The International Atomic Energy Agency (IAEA) has made similar recommendations regarding exemptions in its Safety Series No. 89, "Principles for the Exemption of Radiation Sources and Practices from Regulatory Control." The IAEA has recommended that individual doses not exceed 10 µSv (1 mrem)/yr from each exempt practice. The IAEA's recommendations relate to criteria for exempting whole sources or practices, such as waste disposal or recycling generally, not whether radiation doses from a portion of a given practice, such as the release of gases from a specific geologic repository, may be considered negligible. Finally, the IAEA's recommendations intend their exemption to be for sources and practices "which are inherently safe." It is not clear that the low individual doses or risks projected from gaseous releases from the Yucca Mountain repository should be considered on their own as a "source" or "practice" or that such a source or practice should be considered inherently safe. Also, we believe it to be inappropriate to not calculate a radiation dose merely because the dose rate from a particular source is small.

Further, we are not sure it is appropriate to apply the NIR concept to consideration of population dose. A recent NCRP report questions the application of the negligible incremental dose (NID) concept to consideration of population doses. According to NCRP Report No. 121: "A concept such as the NID (Negligible Incremental Dose) provides a legitimate lower limit below which action to further reduce individual dose is unwarranted, but it is not necessarily a legitimate cut-off dose level for the calculation of collective dose. Collective dose addresses societal risk while the NID and related concepts address individual risk." Based upon this, we think it would be inappropriate to use the negligible incremental dose or risk concept to evaluate whether an individual-protection standard adequately protects the general population.

Although we do not advocate use of the NID concept, we acknowledge that the extremely low levels of individual risk and dose cited by NAS as being associated with the release of ^{14}C from Yucca Mountain are many orders of magnitude below the levels at which we have regulated in other circumstances. For example, we used the following policies under the pre-1990 Clean Air Act (CAA) hazardous air pollution control program: (1) provide public health protection for the greatest number of persons possible based upon a lifetime (70 years) risk level no higher than approximately 1 x 10^{-6} for an individual, and (2) limit the maximum, individual-lifetime, estimated risk to no higher than 1 in 10,000 (1×10^{-4}) (54 FR 51654, 51655, December 15, 1989). Even though we adopted this approach in a different policy context, it provides insight into how we have dealt with similar risk-management issues in a regulatory context. In 1990, Congress amended the CAA to require us to develop technology-based standards to reduce emissions. At the same time, Congress authorized us to delete categories of sources from regulation if no source in that category could cause a lifetime risk of cancer exceeding 1×10^{-6} for the most-exposed individual in the population. The risk over an individual's lifetime from exposure to gaseous ^{14}C released from the Yucca Mountain repository, as estimated by NAS, would be about 100 times lower than 10^{-6}. This particular risk level is extremely low and well below the risk level that we generally regulate.

The disposal standards in 40 CFR part 191 include release limits (or containment requirements) to protect populations and an individual-protection standard. We rejected adopting only an individual-protection standard in those standards because of a concern that an individual-dose limitation alone might encourage selection of disposal sites that relied upon dilution of radionuclides at the expense of increased overall population exposures. Specifically, we were concerned that, in the absence of release limits, "disposal sites near bodies of surface water or large sources of ground water might be preferred--which the Agency believes is an inappropriate policy that would usually increase overall population exposures" (50 FR 38066, 38078, September 19, 1985). For example, it is possible to have a site that could meet the 150 µSv (15 mrem)-CEDE/yr individual-protection standard while still having large numbers of people being exposed to radiation levels just below the standard. This scenario could result in significant numbers of calculated health effects for each generation exposed and very large numbers of calculated health effects over the regulatory period. We believe that the policy embodied in the generic 40 CFR part 191 disposal standards is sound. The provisions in 40 CFR part 191, which could apply to a variety of potential disposal sites, should discourage reliance upon dilution of radionuclides in the general environment as a disposal method.

However, the potential for large-scale dilution of radionuclides, through ground water and into surface water, as modeled in the supporting analyses for 40 CFR part 191, does not exist at Yucca Mountain, thereby minimizing the need for the kind of population-protection requirements found in 40 CFR part 191. Rather, DOE plans to locate the Yucca Mountain repository in an unsaturated rock formation with limited amounts of infiltrating water passing through it and into the underlying tuff aquifer. ("Unsaturated" means that the rock could absorb more water than it is holding.) That aquifer is, in turn, within a ground water system which discharges into arid areas having high evaporation rates and very little surface water. In other words, we believe that the characteristics of the saturated zone under Yucca Mountain are such that dilution from other sources will be limited and the aquifer does not discharge into any large bodies of surface water. Therefore, our basis for inclusion of a population-protection requirement in 40 CFR part 191 does not appear to apply to the development of site-specific standards for Yucca Mountain.

In addition, we based the release limits in 40 CFR part 191 partly upon technology and partly upon risk levels which we believed to be acceptably small. The technology basis for the release limits was based upon assessments of repository performance of several generic disposal systems, including one located in tuff. In finalizing 40 CFR part 191, we stated:

[T]he rule cannot be interpreted as setting precedents for "acceptable risk" levels to future generations that should not be exceeded regardless of the circumstances. Instead, because of a number of unique circumstances, the Agency has been able to develop standards for the management and disposal of these wastes that are both reasonably achievable...and that limit risks to levels that the Agency believes are clearly acceptably small. (50 FR 38066, 38070, September 19, 1985)

We developed these standards during the siting process mandated by the NWPA in the 1980s. The inclusion of release limits pointed to the importance of considering population doses during site selection. We established the standards at a level that appeared to be reasonably achievable for several types of rocks or geologic media and which would keep risks to future populations acceptably small. The assessments we performed in support of these generally applicable standards, however, did not include a gaseous-release pathway similar to that described by NAS for ^{14}C because no one foresaw the potential importance of that pathway at that time. In fact, according to the generic analyses we performed in support of 40 CFR part 191, the unsaturated site in tuff was generally more protective, in terms of limiting total releases, than the other geologic media we evaluated.

For these reasons, we do not believe that these generic analyses and conclusions supporting the development of release limits in 40 CFR part 191 are appropriate for judging the need for population-risk limits or the acceptability of population risks from releases from wastes in the Yucca Mountain disposal system. We are proposing to find that the individual-protection standard is sufficient to protect public health based upon the unique characteristics of the area around the Yucca Mountain site.

In summary, we are proposing to adopt an individual-protection standard for Yucca Mountain that will limit the annual radiation dose incurred by the RMEI to 150 μSv (15 mrem) CEDE. At the same time, we are not proposing to adopt a separate limit on radiation releases for the purpose of protecting the general population, but we are recommending that collective dose be estimated and considered (see the following paragraph). We based this decision upon several factors. The first factor is the NAS projection of extremely small doses to individuals resulting from air releases from Yucca Mountain. That dose level is well below the risk corresponding to our proposed individual-protection standard for Yucca Mountain. It is also well below the level that we have regulated in the past through other regulations. Further, while we decline to establish a general NIR level, we do agree with NAS that estimating the number of health effects resulting from a 0.0003 mrem/yr dose rate, in addition to the dose rate from background radiation, in the general population is uncertain and controversial. The second major factor is that, based upon current and site-specific conditions near Yucca Mountain, there is not likely to be great dilution resulting in exposure of a large population. In addition, we are proposing additional ground water protection standards that would establish specific limits to protect users of ground water and ground water as a resource. Finally, we are still proposing to require that all of the pathways, including air and ground water, would be analyzed by DOE and considered by NRC under the individual-protection standard. We request comment upon this approach. Commenters who disagree with this approach should specifically address why it is inappropriate for the Yucca Mountain disposal system and make suggestions about how we might reasonably address this issue.

While we are not proposing to adopt additional regulatory requirements for collective exposures of the general population from releases from the Yucca Mountain disposal system, we urge DOE to examine design alternatives for the disposal system, for the purpose of reducing potential risk to the general population, in the National Environmental Policy Act (NEPA) process for Yucca Mountain. We received public comments, in response to our request for comments regarding the NAS Report, noting that DOE had already proposed, in its Notice of Intent to prepare a NEPA-prescribed environmental impact statement (EIS) for Yucca Mountain, to evaluate technical alternatives (60 FR 40167, August 7, 1995). In other words, DOE has previously proposed to evaluate technical alternatives as part of its waste containment and isolation strategy for Yucca Mountain (DOE, "Strategy for Waste Containment and Isolation for the Yucca Mountain Site," Preliminary Review Draft, October 9, 1995). Thus, we recommend that DOE incorporate these or similar considerations into its NEPA process to assess the effectiveness of design alternatives to mitigate population exposures.

The following language provides context to the approach we consider appropriate for calculating population exposure in the NEPA process. We recommend that DOE calculate the collective dose without truncation and with full consideration of the appropriate factors. This recommendation is supported by a recent NCRP report upon the principles and application of a collective dose in radiation protection (NCRP Report No. 121). The NCRP advocated the use of collective dose for optimization of protection and provided guidance on future exposures from long-lived radionuclides, the situation that will likely exist at Yucca Mountain:

The most reasonable risk assessment that can be made for such situations is to calculate potential individual doses for a range of scenarios in order to: (1) evaluate protective measures and (2) to try to place some boundaries on estimates of future individual risks. For the few very long-lived radionuclides that are metabolically regulated in the body and more or less uniformly distributed within the biosphere (e.g., ^{14}C and ^{129}I), future average individual doses may be estimated from total quantities in the environment.... (NCRP Report No. 121, pp. 57-58)

III.B.6. What should be assumed about the Future Biosphere?

We propose to require DOE and NRC to use the biosphere assumptions described in this section in all analyses of repository performance, including the performance assessment for determining compliance with the individual-protection standard, the assessment for determining compliance with the ground water standards, and the human-intrusion analysis. Projecting biosphere conditions necessitates making assumptions, many of which are very uncertain and may not be boundable. The NAS stated:

In view of the almost unlimited possible future states of society and of the significance of these states to future risk and dose, ...we have recommended that a particular set of assumptions be used about the biosphere (including, for example, how and where people get their food and water) for compliance calculations...we recommend the use of assumptions that reflect current technologies and living patterns. (NAS Report p. 122)

The NAS also stated:

...unlike our conclusion about the earth science and geologic...factors described [earlier], we believe that it is not possible to predict on the basis of scientific analyses the societal factors that must be specified in a far-future exposure scenario....Any particular scenario about the future of human society near Yucca Mountain...should not be interpreted as reflecting conditions that eventually will occur. Although we recognize the burden on regulators to avoid regulations that are arbitrary, we know of no scientific method for identifying these [exposure] scenarios. (NAS Report p. 96)

We agree with the NAS on this point and propose that speculation concerning some characteristics of the future should not be the focus of the compliance determination process. Instead, we believe that it would be more appropriate to assume that those characteristics will be the same as they are today. No one should interpret this assumption so literally that only current residences and lifestyles of individuals living in the area on the day of promulgation of this part can be considered. Rather, we intend that, based upon current knowledge, DOE and NRC may use those characteristics in combinations in a cautious, but reasonable, manner as input into the Yucca Mountain performance projections. Future characteristics which NRC and DOE may assume to be the same as they are today include the level of human knowledge and technical capability (including medical), human physiology and nutritional needs, general lifestyles of the population, and potential pathways through the biosphere leading to radiation exposure of humans. Also, we propose that it is inappropriate to speculate upon extreme changes in the number of residents, but that consideration should be given to changes in population near the location of the RMEI.

In concert with the NAS Report, we also propose not to allow the assumption that conditions in the future will be the same as present conditions for geologic, hydrologic, and climatic conditions. We are proposing this because we believe the parameter values in the performance assessment which relate to these conditions can be reasonably bounded. We propose to require that these conditions be varied within reasonable bounds over the compliance period and request comment upon this proposed approach.

III.B.7. How far into the Future is it Reasonable to project Disposal System Performance?

The NAS recommended that the time over which compliance should be assessed, that is, the compliance period, should be "the time when the greatest risk occurs, within the limits imposed by long-term stability of the geologic environment" (NAS Report p. 7). The NAS stated that it based this recommendation upon technical, not policy, considerations. However, we believe the selection of the compliance period necessarily involves both technical and policy considerations. For example, NAS stated that we might choose to establish similar policies for managing risks "from disposal of both long-lived hazardous nonradioactive materials and radioactive materials" (NAS Report p. 56). As NAS recognized, we must consider, in this rulemaking, both the technical and policy issues associated with establishing the appropriate compliance period for the performance assessment of the Yucca Mountain disposal system.

We request public comment upon two alternatives for the compliance period for the individual-protection standard. One alternative is to adopt a compliance period that is the time to peak dose within the period of geologic stability. The second alternative is to adopt a time period during which the repository must meet the disposal standards. For the reasons described below, we believe that the second alternative is preferable. Therefore, we are proposing that the peak dose within 10,000 years after disposal must comply with the individual-protection standard. Also, the EPA-preferred approach would require calculation of the peak dose within the period of geologic stability. It does not, however, apply a quantitative limit after 10,000 years. The intent of examining disposal system performance after 10,000 years is to estimate the long-term performance of the disposal system to see if dramatic changes in the performance of the disposal system could be anticipated. We would require DOE to include the results and bases of the additional analysis in the EIS for Yucca Mountain as an indicator of the future performance of the disposal system. This analysis also would serve as another source of information for decisionmakers in making both design and licensing decisions. However, NRC is not to use the additional analysis in determining compliance with proposed § 197.20.

The principal tool used to assess compliance with the individual-protection standard is a quantitative performance assessment. This method relies upon modeling of the potential processes and events leading to releases of radionuclides from the disposal system, subsequent radionuclide transport, and consequences upon health. To consider compliance for any length of time, several facets of knowledge and technical capability are necessary. First, the scientific understanding of the relevant, potential processes and events leading to releases must be sufficient to allow a quantitative estimate of projected repository performance. Second, adequate analytical methods and numerical tools must exist to incorporate this understanding into a quantitative assessment of compliance. Third, scientific understanding, data, and analytical methods must be adequately developed to allow evaluation of performance with sufficient robustness to judge compliance with reasonable expectation over the regulatory period. Finally, the analyses must be able to produce estimated results in a form capable of comparison with the standards.

The NAS evaluated these requirements for Yucca Mountain and concluded that those aspects of disposal system and waste behavior that depend upon physical and geologic properties can be estimated within reasonable limits of uncertainty. Also, NAS believed that these properties and processes are sufficiently understood and boundable over the long periods at issue to make such calculations possible and meaningful. The NAS acknowledged that these factors cannot be calculated precisely, but concluded that there is a substantial scientific basis for making such calculations. The NAS concluded that by taking uncertainties and natural variabilities into account, it would be possible to estimate, for example, the concentration of radionuclides in ground water at different locations and the times of gaseous releases. Second, NAS concluded that the mathematical and numerical tools necessary to evaluate repository performance are available or could be developed as part of the standard-setting or compliance-determination processes. Third, NAS concluded that: “So long as the geologic regime remains relatively stable, it should be possible to assess the maximum risks with reasonable assurance” (NAS Report p. 69). The NAS used the term "geologic stability" to describe the situation where geologic processes, such as earthquakes and erosion, that could affect the performance assessment of the Yucca Mountain site are active (not static) and are expected to occur. Based upon the use of the terms “stable” and “boundable” throughout the NAS Report, one can infer that NAS applied the term “geologic stability” or “stable” to the situation where the rate of processes and numeric range of individual physical properties could be bounded with reasonable certainty. The subsequent use of the term "stable" will not imply static conditions or processes. Rather, it will describe the properties and processes that can be bounded. Finally, NAS found that the established procedures of risk analysis should enable the results of each performance simulation of the disposal system to be combined into a single estimate for comparison with the standard.

Time to peak dose within the period of geologic stability. The NAS recommended that the compliance period for the Yucca Mountain disposal system be the time to peak risk within the long-term stability of the geologic environment. Since the time to peak risk is generally the time to peak dose, subsequent discussion of the NAS findings will refer to the time to peak dose. The "peak dose" is the mean value of the range of the highest potential annual doses, as determined by the performance assessment, incurred by the RMEI within the compliance period. The NAS based its recommendation to use the time to peak dose upon its review of:

(1) the technical analyses supporting 40 CFR part 191;

(2) information derived from current performance assessments of the Yucca Mountain disposal system; and

(3) the geologic and physical processes that could affect the release and transport of radionuclides to the biosphere.

The 40 CFR part 191 standards contain a compliance period of 10,000 years. There were three reasons that we set this time frame:

(1) after that time, there is concern that the uncertainties in compliance assessment become unacceptably large (50 FR 38066, 38076, September 19, 1985);

(2) there are likely to be no exceptionally large geologic changes during that time (47 FR

58196, 58199, December 29, 1982); and

(3) using time frames of less than 10,000 years does not allow for valid comparisons among potential sites. For example, for 1,000 years, all of the generic sites analyzed appeared to contain the waste approximately equally because of long ground water travel times at well-selected sites (47 FR 58196, 58199, December 29, 1982).

One purpose of geologic disposal is to provide long-term barriers to the movement of radionuclides into the biosphere (NAS Report p. 19). As described earlier, the Department plans to locate the Yucca Mountain repository in tuff about 300 meters above the local water table. When nongaseous radionuclides are released from the waste packages, they most likely will be transported by rain water that moves from the surface both horizontally within individual tuff layers and vertically downward, through fractures in the tuff layers, toward the underlying aquifer. Once the radionuclides reach the aquifer, they will be carried away from the repository in the direction of ground water flow. The most probable route for exposing humans to radiation resulting from releases from the Yucca Mountain disposal system is via withdrawal of contaminated water for local use. In the case of Yucca Mountain, DOE estimates that most radionuclides would not reach currently populated areas within 10,000 years (see the BID).

While this finding alone seems to indicate that the compliance period for Yucca Mountain should be longer than 10,000 years to be protective, NAS concluded that the need to consider the exposures when they are calculated to occur must be weighed against the problem of cumulative uncertainty. As noted above, exposures could occur over tens- to hundreds-of-thousands of years. However, as the compliance period is extended to such lengths, uncertainty increases and the resulting projected doses are increasingly meaningless from a policy perspective. The NAS stated that there are significant uncertainties in a performance assessment and that the overall uncertainty increases with time. Even so, NAS found that, "...there is no scientific basis for limiting the time period of the individual-risk standard to 10,000 years or any other value" (NAS Report p. 55). Estimates by NRC and DOE related to the Yucca Mountain disposal system have indicated wide differences in estimates of the time that radionuclides may take to reach the biosphere and cause the peak dose to occur (see the BID). However, while the results have indicated that the time to peak dose may vary anywhere from a few tens-of-thousands to hundreds-of-thousands of years, the estimated values of the peak doses, while separated in time, are similar in magnitude (see the BID). These estimates differ because the analysts used different assumptions and conceptual models for flow and transport of radionuclides through the Yucca Mountain unsaturated zone. We believe that this situation will exist independently of the compliance-period issue. The NAS also stated that data and analyses of some of the factors that are uncertain at one time might be more certain at a later time. For example, there is uncertainty as to how many waste packages might fail in the near term. However, at some later time in the distant future, the uncertainty is very small because when enough time has passed, all of the packages will fail (NAS Report p. 72). Also, NAS stated that many of the uncertainties in parameter values describing the geologic system are not due to the length of time but rather to the difficulty in estimating values of site characteristics which vary across the site. We believe that these difficulties are always present and that analysts must consider them in the compliance assessment for any period chosen (NAS Report p.72).

As NAS noted, evaluating compliance with the 40 CFR part 197 standards depends upon being able to:

(1) understand and model radionuclide-transport processes and the processes and events that might lead to transport;

(2) use appropriate analytical methods to determine the levels of human exposure;

(3) quantify or bound the probabilities of the processes and events, including the related uncertainties; and

(4) state the results in a form capable of being compared with the standards.

The NAS reviewed how radionuclides might enter the biosphere in order to determine the feasibility of evaluating them in a compliance assessment. In addition, to determine whether the modifying processes should also be evaluated in a compliance assessment, NAS analyzed the geologic and physical processes that could modify the properties of the contaminant-containing media and processes by which radionuclides are moved.

The radionuclide-transport processes evaluated by NAS included:

(1) release from the waste form;

(2) transport from canisters into the near-field (near the waste canisters) unsaturated zone;

(3) gas-phase transport from the unsaturated zone into the atmosphere around Yucca Mountain;

(4) atmospheric circulation leading to dispersal of gaseous radionuclides in the global atmosphere;

(5) aqueous-phase transport from the unsaturated zone to the water table; and

(6) transport of radionuclides through the saturated zone beneath the repository to other locations from which water may be extracted by humans or ultimately reach the surface at a discharge area (NAS Report pp. 85 - 90).

The NAS concluded that these processes are “sufficiently quantifiable and the uncertainties are sufficiently boundable that they can be included in performance assessments that extend over time frames corresponding to those over which the geologic system is relatively stable or varies in a boundable manner” (NAS Report p. 85). The NAS concluded that the “geologic record suggests that this time frame is on the order of about one million years” (NAS Report pp. 9 and 85). Likewise, NAS concluded that the probabilities and consequences of these processes and events that could modify the way in which radionuclides are moved in the vicinity of Yucca Mountain, including climate change, seismic activity, and volcanic eruptions, “are sufficiently boundable so that these factors can be included in performance assessments that extend over periods on the order of about one million years” (NAS Report p. 91).

Thus, NAS recommended, on a technical basis, that the compliance period for the protection of the individual should extend to the time of the peak dose during the period in which geologic processes are stable or boundable. This would require determining compliance and licensing the disposal system on the basis of projections of performance over tens- to hundreds-of-thousands of years into the future. We believe that such an approach is not practical for Yucca Mountain.

As noted earlier, NAS concluded that “there is no scientific basis for limiting the time period of the individual-risk standard to 10,000 years or any other value.” Nevertheless, there is still considerable uncertainty as to whether current modeling capability allows development and validation of computer models that will provide sufficiently meaningful projections over a time frame up to tens-of-thousands to hundreds-of-thousands of years. Simply because such models can provide projections for those time periods does not mean those projections are either meaningful for decisionmakers or accurate. Furthermore, we are not aware of a policy basis that we could use to determine the level of proof or confidence necessary to determine compliance based upon projections of hundreds-of-thousands of years into the future. While NAS indicated that analyses of the performance of the Yucca Mountain disposal system dealing with the far future can be bounded, a large and cumulative amount of uncertainty is associated with those numerical projections. Setting a strict numerical standard at a level of risk acceptable today for the period of geologic stability would tend to ignore this cumulative uncertainty. For example, if the performance assessment indicates that the peak dose occurs 600,000 years in the future at an annual CEDE that has an uncertainty range of 0.1 mrem to 10,000 mrem, does that indicate that the disposal system is safe or unsafe and should NRC license it or not? In light of the cumulative uncertainty for calculations over an extremely long time, it may be more appropriate to consider, in a regulatory decisionmaking, assessments of disposal system performance over such time in a qualitative manner. We request comments upon the reasonableness of adopting the NAS-recommended compliance period or some other approach in lieu of the 10,000-year compliance period which we favor and describe below. We also seek comment upon whether the NAS-recommended compliance period can be implemented in a reasonable manner and how that could be done.

A 10,000-year compliance period (proposed § 197.20). As noted earlier, the selection of the compliance period for the individual-protection standard involves both technical and policy considerations. It is our responsibility to weigh both during this rulemaking. In addition to the technical guidance provided in the NAS Report, we have considered several policy and technical factors that NAS did not fully address.

First, as suggested by NAS, we evaluated the policies for managing risks from the disposal of both long-lived, hazardous, nonradioactive materials and radioactive materials. Second, we evaluated consistency with both 40 CFR part 191 and the issue of consistent time periods for the protection of ground water resources and public health. Third, we considered the issue of uncertainty in predicting dose over the very long periods contemplated in the alternative of peak dose within the period of geologic stability. Finally, we reviewed the feasibility of implementing the alternative of peak risk within the period of geologic stability, as recommended by NAS. As a result of these considerations, we are proposing a 10,000-year compliance period with a quantitative limit and a requirement to calculate the peak dose, using performance assessments, if the peak dose occurs after 10,000 years. Under our proposal, the performance assessment results for the post-10,000-year period must be made part of the public record by DOE including it in the EIS for Yucca Mountain.

In its discussion of the policy issues associated with the selection of the time period for compliance, NAS suggested that we might choose to establish consistent risk-management policies for long-lived, hazardous, nonradioactive materials and radioactive materials. We previously addressed the 10,000-year compliance period in the regulation of hazardous waste subject to land-disposal restrictions. Land disposal, as defined in 40 CFR 268.2(c), includes, but is not limited to, any placement of hazardous waste in land-based units such as landfills, surface impoundments, and injection wells. Facilities may seek an exemption by demonstrating that there will be no migration of hazardous constituents from the disposal unit for as long as the waste remains hazardous (40 CFR 268.6). We have interpreted the phrase “for as long as the waste remains hazardous” to mean that the no-migration demonstration shows that hazardous constituents will not exceed acceptable concentration levels for as long as the constituents retain the potential to harm human health and the environment. This period may include not only the operating phase of the facility, but also what may be an extensive period after facility closure. With respect to injection wells, we have specifically required a demonstration that the injected fluid will not migrate within 10,000 years (40 CFR 148.20(a)). We chose the 10,000-year performance period referenced in our guidance upon no-migration petitions, in part, to be equal to time periods cited in draft or final DOE, NRC, and EPA regulations (10 CFR 960, 10 CFR 60, or 40 CFR 191, respectively) governing siting, licensing, and releases from HLW disposal systems. With respect to other land-based units regulated under the Resource Conservation and Recovery Act (RCRA) hazardous-waste regulations, we concluded that the compliance period is specific to the waste and site under consideration. For example, for the WIPP no-migration petition, we found that "it is not particularly useful to extend this model beyond 10,000 years into the future.... [However, t]he agency does believe...that modeling over a 10,000-year period provides a useful tool in assessing the long-term stability of the repository and the potential for migration of hazardous constituents" (55 FR 13068, 13073, April 6, 1990).

Second, the individual-protection requirements in 40 CFR part 191 (58 FR 66398, 66414, December 20, 1993) have a compliance period of 10,000 years. The part 191 standards apply to the same types of waste and type of disposal system as proposed for Yucca Mountain. However, as we explained in the What Led up to Today's Action? section earlier in this notice, by statute the part 191 requirements do not apply to Yucca Mountain. If we finally adopt the 10,000-year compliance period, it would require the same compliance period for the Yucca Mountain disposal system as for other disposal systems subject to 40 CFR part 191. Such a requirement would be consistent with 40 CFR part 191, which we deem appropriate since both sets of standards apply to the same types of waste.

Third, we are concerned that there might be large uncertainty in projecting human exposure due to releases from the repository over extremely long periods. We agree with the NAS conclusion that it is possible to evaluate the performance of the Yucca Mountain disposal system and the lithosphere within certain bounds for relatively long periods. However, we believe that NAS might not have fully addressed two aspects of uncertainty.

One of the aspects of uncertainty relates to the impact of long-term natural changes in climate and its effect upon choosing an appropriate RMEI. For extremely long periods, major changes in the global climate, for example, a transition to a glacial climate, could occur (see the BID). However, over the next 10,000 years, the biosphere in the Yucca Mountain area will probably remain, in general, similar to present-day conditions due to the rain-shadow effect of the Sierra Nevada Mountains, which lie to the west of Yucca Mountain (see the BID). For the longer periods contemplated for the alternative of time to peak dose, the global climate regime is virtually certain to pass through several glacial-interglacial cycles, with the majority of time spent in the glacial state (NAS Report p. 91). These longer periods would require the specification of exposure scenarios that would not be based upon current knowledge or cautious, but reasonable, assumptions, but rather upon potentially arbitrary assumptions. The NAS indicated that it knew of no scientific basis for identifying such scenarios (NAS Report p. 96). It is for these reasons that such extremely long-term calculations are useful only as indicators, rather than accurate predictors, of the long-term performance of the Yucca Mountain disposal system (IAEA TECDOC-767, 1994).

The other aspect of uncertainty concerns the range of possible biosphere conditions and human behavior. It is necessary to make certain assumptions regarding the biosphere, even for the 10,000-year alternative, because the period of 10,000 years represents a very long compliance period for current-day assessments to project performance. For example, it is twice as long as recorded human history (see the What should be assumed about the Future Biosphere? section earlier in this notice). For periods approaching the 1,000,000 years that NAS contemplated under the peak-dose alternative, even human evolutionary changes become possible. Thus, reliable modeling of human exposure may be untenable and regulation to the time of peak dose within the period of geologic stability could become arbitrary.

Fourth, many international geologic disposal programs use a 10,000-year regulatory compliance period as a requirement.

Finally, an additional complication associated with the time to peak dose within the period of geologic stability is that it could lead to a period of regulation that has never been implemented in a national or international radiation regulatory program. Focusing upon a 10,000-year compliance period forces more emphasis upon those features over which man can exert some control, such as repository design and engineered barriers. It is unlikely that over much longer time frames that any engineered barrier will be effective. Those features, the geologic barriers, and their interactions define the waste isolation capability of the disposal system. By focusing upon an analysis of the features that man can influence or dictate at the site, it may be possible to influence the timing and magnitude of the peak dose, even over times longer than 10,000 years.

Thus, we request comment upon our proposal of a 10,000-year compliance period to judge compliance with proposed § 197.20 and our proposal to require consideration of the peak dose, using performance assessments, if it occurs after 10,000 years. Again, after 10,000 years, we would not require the calculated level to comply with a specific numerical standard but we would require its consideration as an indicator of longer-term performance and be included in the EIS for Yucca Mountain.

We also request comment upon the appropriateness of a 10,000-year compliance period for the individual-protection standard. Commenters should address the issues that we should consider in determining the appropriate compliance period. We also specifically request comments upon whether the NAS' recommendation of the time to peak dose within the period of geologic stability can be implemented reasonably and, if so, how that could be done.

III.C. What are the Requirements for Performance Assessments and Determinations of Compliance? (proposed §§ 197.20, 197.25, and 197.35)

III.C.1. What Limits are there on Factors included in the Performance Assessments?

The Commission is responsible for deciding whether or not to license the Yucca Mountain disposal system. It must make that decision based largely upon whether DOE has demonstrated compliance with our standards in 40 CFR part 197. Under the proposed 40 CFR part 197, the quantitative analysis underlying that decision will be a performance assessment (the proposed definition of "performance assessment" is in § 197.12). We are proposing that performance assessments be a requirement of licensing. The EnPA requires that the Commission modify its technical requirements for licensing the disposal system to be consistent with our final 40 CFR part 197 standards. Therefore, our standards would require DOE to complete a performance assessment prior to applying for a license and would require NRC to determine, taking into consideration that performance assessment, whether the disposal system's projected performance complies with § 197.20.

We also are proposing, consistent with the performance assessment requirements in 40 CFR part 191:

(1) to exclude from performance assessments those natural processes and events whose likelihood of occurrence is so small that they are very unlikely;

(2) that such performance assessments need not include categories of processes or events that DOE and NRC estimate to have less than a 1 in 10,000 (1×10^{-4}) chance of occurring during the 10,000 years after disposal. Probabilities below this level are associated with events such as the appearance of new volcanoes outside of known areas of volcanic activity or a cataclysmic meteor impact in the area of the repository. We believe there is little or no benefit to public health or the environment from trying to regulate the effects of such very unlikely events; and

(3) that the performance assessment need not evaluate, in detail, the releases from processes, events, and sequences of processes and events estimated to have a likelihood of occurrence greater than 1×10^{-4} of occurring during the 10,000 years following disposal, if there is a reasonable expectation that the time to, or the magnitude of, the peak dose would not be changed significantly by such omissions. As necessary, the Commission may provide specific guidance upon scenario selection and characterization to assure that processes or events are not excluded inappropriately.

A related issue upon which we request comment is if there is a period of the geologic record which we should require DOE and NRC to use to calculate the probability of processes and events occurring. The probability of a geologic event, such as an earthquake, occurring in the future typically comes from evidence of previous events which is preserved in, and can be dated by using, the geologic record. We believe that the geologic record is best preserved in the relatively recent past.

We are also proposing to require that DOE and NRC use quantitative assessments to determine compliance with the human-intrusion and ground water protection standards (see the What is the Standard for Human Intrusion? and How will Ground Water be Protected? sections later in this notice). The human-intrusion analysis would require a separate assessment of the effects of human intrusion upon the resilience of the Yucca Mountain disposal system. Following the recommendation of NAS, we intend the analysis to be an assessment of the disposal system's isolation capability following a single, stylized, human intrusion. The analysis required to determine compliance with the ground water protection standards applies only to undisturbed performance.

We are proposing to allow the exclusion of unlikely natural events from both the ground water and human-intrusion assessments. The approach for the ground water protection requirements is consistent with subpart C of 40 CFR part 191, “Environmental Standards for Ground-Water Protection” while the approach for the human-intrusion assessment is consistent with the NAS recommendation (see the What is the Standard for Human Intrusion? section later in this notice). We request public comment upon whether this approach is appropriate for Yucca Mountain.

III.C.2. Is Expert Opinion Allowed?

The quantitative requirements in proposed subpart B of part 197 require:

(1) evaluation of processes, events, and sequences of processes and events leading to radionuclide releases from the disposal system;

(2) estimation of the resulting doses or radionuclide concentrations; and

(3) estimation of the likelihood of the resulting doses or radionuclide concentrations.

The likelihood of the processes, events, and sequences of processes and events occurring should be estimated by DOE and NRC based upon current scientific knowledge of previous occurrences. However, it is likely that there will be processes, events, and sequences of processes and events which have not occurred or occurred too infrequently to be statistically significant. This situation will require the use of expert opinion, for example, scientific and engineering expertise, to arrive at cautious, but reasonable, estimates of the probability of future occurrence. Also, there likely will be many other areas where DOE could use expert opinion, for example, when there are multiple models applicable to the performance assessment or human-intrusion analysis, or significant uncertainties in the variation of parameter values.

There are two commonly used methods for the gathering of expert opinion, namely, expert judgment and expert elicitation. Expert judgment is typically obtained informally from one or more individuals and is noted by the person(s) seeking the judgment in documentation used to support the activity. In contrast, expert elicitation is a formal, structured, and thoroughly documented process. Whether it is appropriate to conduct an expert elicitation depends upon the issue under consideration.

We have considered setting guidelines for the use of expert elicitation. The type of guidelines we considered could include one or all of the following requirements when expert elicitation is used: (1) the Commission needs to consider the source and use of the information so gathered; (2) we would expect the Commission to assure that, to the extent possible, experts with both expertise appropriate for the subject matter and independence from DOE will be on the expert elicitation panel consulted to judge the validity and adequacy of the model(s) or value(s) for use in a compliance assessment; and (3) when DOE presents information to the expert elicitation panel, it should do so in a public meeting, and qualified experts, such as representatives of the State, should be given an opportunity to present information.

If we were to set any requirement, we would have to consider whether NRC may allow DOE to use expert elicitations, which did not follow these rules but were completed prior to the effective date of part 197, for the purpose of determining compliance with the provisions of part 197. We believe that it would probably be an unnecessary use of time and resources to require such work to be repeated or not be used if the Commission judges them to be acceptable.

We request comment upon whether it is appropriate for us to set guidelines for the use of expert opinion in this standard and, if so, what those guidelines should be.

III.C.3. What Level of Expectation is required for NRC to Determine Compliance?

While the provisions in this rule establish minimum requirements for implementation of the disposal standards, NRC may establish requirements that are more stringent. As mentioned in the previous section, we are proposing the concept of “reasonable expectation” to reflect our intent regarding the level of "proof" necessary for NRC to determine whether the projected performance of the Yucca Mountain disposal system complies with the standards (see proposed §§ 197.20, 197.25, and 197.35). We intend for this term to convey our position and intent that unequivocal numerical proof of compliance is neither necessary nor likely to be obtainable. The NRC has used a similar qualitative test, "reasonable assurance," for many years in its regulations. However, the NRC regulations are focused upon engineered systems with relatively short lifetimes, for example, nuclear power reactors. We believe that for very long-term projections, involving the interaction of natural systems with the engineered system and the uncertainties associated with the long time periods involved, a different approach may be more appropriate.

Therefore, we are proposing to require that the test of disposal system compliance be a "reasonable expectation" that the standards will be met. In carrying out performance assessments under a “reasonable expectation” approach, all parameters that significantly affect performance would be identified and included in the assessments. The distribution of values for these parameters would be made to the limits of confidence possible for the expected conditions in the natural and engineered barriers and the inherent uncertainties involved in estimating those values. Selecting parameter values for quantitative performance assessments would focus upon the full range of defensible and reasonable parameter distributions rather than focusing only upon the tails of the distributions as is more commonly done under the “reasonable assurance” approach. The “reasonable expectation” approach also would not exclude important parameters from the assessments because they are difficult to quantify to a high degree of confidence. Some parameters, such as corrosion rates for metal container components, may be quantified with a high degree of accuracy and precision. Others, such as the amount of water entering a waste emplacement drift and dripping onto a waste package, cannot be quantified with a high degree of accuracy and precision, but are very important to a realistic assessment of performance. Overestimating or underestimating the values of parameters, or ignoring the positive effects upon performance for other processes and parameters because they cannot be precisely estimated, would essentially result in the performance assessments actually being analyses of extreme performance scenarios. These extreme assessments have a high probability of being unrealistic or of such low probability that they would not represent the range of likely performance for the disposal system.

We note that if the compliance period for the individual-protection standard extended to the time of peak dose within the period of geologic stability (which NAS estimated to be one million years for the Yucca Mountain site), this test would allow for decreasing confidence in the numerical results of the performance assessments as the compliance period increases beyond 10,000 years. For example, this means that the weight of evidence necessary, based upon reasonable expectation, for a compliance period of 10,000 years would be greater than that required for a compliance period of hundreds of thousands of years.

III.D. Are there Qualitative Requirements to help assure Protection?

In addition to the quantitative limits in the standards, we considered several qualitative principles called "assurance requirements." We considered including such requirements because of the uncertainties that exist in projecting the effects of releases from radioactive waste over long periods. The intent for such assurance requirements would be to add confidence that the Yucca Mountain disposal system will achieve the level of protection proposed in the quantitative standards. This is the same approach that we require in 40 CFR part 191 and would provide similar protection regarding Yucca Mountain. The NAS also recognized the need for protection beyond that provided by the disposal system when it addressed institutional controls in its Report (NAS Report p. 11).

The assurance requirements we considered included the use of passive and active institutional controls, monitoring, the use of multiple barriers to isolate waste, and the ability to locate and remove the waste after disposal. In 40 CFR part 191, there is a sixth assurance requirement, 40 CFR 191.14(e), which we consider to be inappropriate for the Yucca site. The purpose of that requirement is to avoid sites where there are resources that might increase the likelihood of human intrusion. Congress specifically designated the Yucca Mountain site for characterization, so avoiding sites close to resources is not relevant in this instance. Further, the EnPA specifically dictates that we establish standards for the Yucca Mountain site so the intent of influencing site selection does not apply here.

We recognize that no one can accurately project the increase of protection brought by these assurance requirements. Under 40 CFR part 191, which we promulgated under the authority of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2022), NRC is exempted from the assurance requirements because it included equivalent provisions in 10 CFR part 60, the NRC regulations which implement 40 CFR part 191. The EnPA requires NRC to modify its technical requirements and criteria to be consistent with our standards for Yucca Mountain. We request comment upon whether it is appropriate for us to establish assurance requirements in 40 CFR part 197, and if so, what those requirements should be.

III.E. What is the Standard for Human Intrusion? (proposed § 197.25)

Previous standards and regulations for radioactive waste disposal, for example, 40 CFR part 191 for SNF and HLW and 10 CFR part 61 for LLW, included consideration of inadvertent human intrusion which could affect the release rate from, and the resultant quantity of radionuclides leaving, a disposal system.

In section 801(a)(2)(B) of the EnPA, Congress inquired about whether active institutional controls could effectively stop human intrusion into the Yucca Mountain disposal system (see Background on and Summary of the NAS Report section earlier in this notice). In its Report, NAS concluded that the answer to this question was “no” (NAS Report p. 11). The NAS reasoned that an answer of "yes" would require assumptions that active institutional controls will endure and that future generations are willing to dedicate resources for this purpose for a period longer than recorded human history. In support of its opinion, NAS stated, “that there is no scientific basis for making projections over the long term of either the social [or] institutional...status of future societies” (NAS Report p. 106).

It was NAS' opinion that human intrusion is plausible at Yucca Mountain and that the standards should, therefore, include consideration of the effects of human intrusion. In order to assess the effects of human intrusion, one must determine the probability of its occurrence sometime in the future and the consequences of that intrusion. Whether it is possible to predict the probability or frequency of human intrusion in a scientifically supportable manner was the third and final question posed by Congress in the EnPA (section 801(a)(2)(C)). The NAS concluded “that there is no technical basis for predicting either the nature or the frequency of occurrence of intrusions” and that although accurate prediction of the frequency of human intrusion is not possible, calculations can project potential consequences of assumed human-intrusion events (NAS Report p. 106). The NAS thus recommended that we assume that an intrusion will occur and that we specify an intrusion scenario for DOE and NRC to use to evaluate the "resilience" of the repository. The NAS stated: "The key performance issue is whether repository performance would be substantially degraded as a consequence of an inadvertent intrusion...." (NAS Report p.

121).

In following that recommendation, we are proposing a single-borehole intrusion scenario based upon Yucca Mountain-specific conditions. The intended purpose of analyzing this scenario "...is to examine the site- and design-related aspects of repository performance under an assumed intrusion scenario to inform a qualitative judgment" (NAS Report p. 111). The assessment would result in a calculated RMEI dose arriving through the pathway created by the assumed borehole (with no other releases included). Consistent with the NAS Report, we also are proposing "that the conditional risk as a result of the assumed intrusion scenario should be no greater than the risk levels that would be acceptable for the undisturbed-repository case" (NAS Report p. 113). We are proposing to interpret the NAS' term "undisturbed" to mean that the Yucca Mountain disposal system is not disturbed by human intrusion but could be disturbed by other processes or events which are likely to occur.

We also are proposing that the human-intrusion analysis of repository performance use the same methods and RME characteristics for the performance assessment as those required for the individual-protection standard, with two exceptions. Those exceptions are that the human-intrusion analysis would exclude unlikely natural events and that the analysis would only address the releases occurring through the borehole (see the <u>What are the Requirements for Performance Assessments and Determinations of Compliance?</u> section earlier in this notice).

Concerning intentional intrusion, NAS concluded that: "We also considered intentional intrusion...but concluded that it makes no sense...to try to protect against the risks arising from the conscious activities of future human societies" (NAS Report p. 114). We agree with this conclusion and propose to find it acceptable to exclude long-term or deliberate, as opposed to acute and inadvertent, human disturbance of the disposal system from the human-intrusion analysis on the theory that society could retain at least some general knowledge of the disposal system and, therefore, would know that such actions could be dangerous. The proposed human-intrusion scenario, therefore, includes only an acute, inadvertent intrusion.

Description of the proposed human-intrusion scenario. To develop an appropriate scenario, we reviewed information about known resources and geologic characteristics of the Yucca Mountain site associated with past and current drilling for resources in the area surrounding Yucca Mountain that could have an effect upon the type of proposed human-intrusion scenario (see the BID). Based upon this examination, we are proposing to adopt the NAS-suggested starting point for a human-intrusion scenario. That scenario is a single, stylized intrusion through the repository to the underlying aquifer based upon current drilling practices. The proposed scenario presumes that the intrusion occurs because of exploratory drilling for water. There are a number of reasons why people in the future could be drilling within the repository area, e.g., archeological pursuits, mineral exploration, or geological investigations. However, we believe that drilling for water is, for regulatory purposes, the best example of an intrusion scenario. The choice of exploratory drilling for water is not a prediction that this type of intrusion will occur or that it will occur on the surface slopes overlying the repository but it is necessary to fulfill the NAS' consideration that a borehole "of specified diameter [is] drilled from the surface through a canister of waste to the underlying aquifer" (NAS Report p. 111). Exploratory drilling for water, using current technology, essentially fixes the diameter of the borehole and drilling from the surface necessarily places the drill rig somewhere above the repository, but not necessarily on the crest of Yucca Mountain. For purposes of determining compliance with the human-intrusion standard, DOE must calculate the CEDE incurred by the RMEI using only releases through the pathway created by the assumed borehole (with no other releases included).

Under our proposal, NRC would specify when the intrusion would occur based upon the earliest time that current technology and practices could lead to waste package penetration. However, it must not occur sooner than the cessation of active institutional controls (see the Are there Qualitative Requirements to help assure Protection? section earlier in this notice). In general, we believe that the time frame for the drilling intrusion should be within the period that a small percentage of the waste packages have failed but before significant migration of radionuclides from the engineered barrier system has occurred since, based upon our understanding of drilling practices, this would be about the earliest time that impact with a waste package would not be recognized by a driller. Our review of information about drilling and experiences of drillers indicates that special efforts, for example, changing to a specialized drill bit, would likely be necessary to penetrate intact, nondegraded waste packages of the type DOE plans to use. As stated earlier, NRC would determine the timing as part of the licensing process. The Department's waste-package performance estimates indicate that a waste package would be recognizable to a driller for at least thousands of years (see the BID).

This is consistent with NAS' example scenario (NAS Report pp. 111-112). It requires evaluation of a single, nearly vertical borehole from the surface that breaches the repository, passes through a degraded waste package, and reaches the water table. We also are proposing that careful sealing of the borehole does not occur, but that natural processes gradually modify the transport characteristics within the borehole. In determining compliance, we are proposing that it is appropriate to assume that the result is no more severe than the creation of a ground water flow path from the crest of Yucca Mountain through the repository and into the ground water table. By proposing this single-borehole, single-waste-package scenario, we are not suggesting that other forms or types of human intrusion, or that intrusion as a result of a resource other than water, will not occur. For example, we know of different drilling techniques such as slanted, horizontal, and robotic which, in theory, could result in more penetrated waste packages. However, we do not believe that more complex scenarios would provide more information about the resilience of the repository than would the proposed scenario.

We also considered use of a human-intrusion scenario consistent with that required in EPA’s criteria for certifying WIPP (40 CFR part 194). These criteria required DOE to identify the rate of resource drilling in the area surrounding the WIPP for the past 100 years (approximately the period of recorded history for drilling events in the area). DOE was required to then use this drilling rate in its performance assessment to determine the number of intrusions into the repository over the 10,000-year regulatory period. We considered this approach appropriate for the WIPP facility given the considerable amount of drilling in the vicinity of the site. We chose not to propose this approach for the Yucca Mountain facility given the recommendation in the NAS Report. We request comment upon the reasonableness of the proposed human-intrusion scenario, and whether an approach similar to that used for WIPP is more appropriate.

As noted earlier, we are proposing to use the same RME descriptors for this analysis and scenario as in the assessment for compliance with the individual-protection standard. While one could postulate that an individual occupies a location above the repository footprint in the future and is impacted by radioactive material brought to the surface during an intrusion event, the level of exposure of such an individual would be independent of whether the repository performs acceptably when breached by human intrusion in the manner prescribed in the proposed scenario. Movement of waste to the surface as a result of human intrusion is an acute action with the resulting exposure being a direct consequence of that action. Thus, we propose to interpret the NAS-recommended test of "resilience" to be a longer-term test as measured by exposures caused by releases which occur gradually through the borehole, not suddenly as with direct removal. In addition, the effects of direct removal depend upon the specific parameters involved with the drilling and not upon the containment characteristics of the disposal system. We also are proposing that the test of the resilience of the repository system be the dose incurred by the same RMEI as determined for the individual-protection standard. This is consistent with the NAS' recommendation.

We request comment upon how much the human-intrusion analysis will add to protection of public health. Also, given current drilling practice in the vicinity of Yucca Mountain, we seek comment upon whether our proposed, stylized, human-intrusion scenario is reasonable.

<u>Time frame for the analysis</u>. We are considering two approaches to determine how far into the future that the human-intrusion analyses will be required to project doses. In the first approach, which is proposed in §§ 197.25 and 197.26, we would require the peak dose during the first 10,000 years, as a result of human intrusion, to be less than 150 µSv/yr (15 mrem)/yr). In the second approach, DOE would calculate the earliest time that the engineered barrier system would degrade sufficiently that current drilling techniques could lead to complete waste package penetration without recognition by the drillers. If that intrusion can happen within 10,000 years, then DOE must do an analysis which projects the peak dose that would occur as a result of the

intrusion within 10,000 years. That dose would have to be less than 150 µSv/yr (15 mrem/yr) for the site to be licensed, considering reasonable expectation. If the undetected intrusion could not occur until after 10,000 years, then DOE would still do the analysis, however the results would not be part of the licensing process but would be included in the Yucca Mountain EIS. This approach mirrors the way that the 10,000-year and post-10,000-year analyses are proposed in the individual-protection standard. This approach has the advantage of encouraging DOE to use a robust engineered design. We request comment upon the appropriateness of using either of these alternatives.

III.F. How will Ground Water be Protected? (proposed § 197.35)

Ground water is a valuable resource with many potential uses. Our proposed ground water protection standards would protect ground water that is being used or might be used as drinking water by restricting potential future contamination. Water from the aquifer which flows beneath Yucca Mountain is currently being used as a source of drinking water 20 to 30 km south of Yucca Mountain in the communities directly protected by the individual-protection standard. It is also a potential source of drinking water for more distant communities and, theoretically, could supply drinking water for several hundred thousand people. For these reasons, we believe it is a resource that needs to be protected. Therefore, we are proposing to protect the ground water to the same level as the maximum contaminant levels (MCLs) for radionuclides which we have established under the authority of the Safe Drinking Water Act (SDWA). This is also consistent with our policy for ground water protection as stated in “Protecting the Nation’s Ground Water: EPA’s Strategy for the 1990s” ("the Strategy," EPA 21Z-1020, July 1991). In addition to drinking water, ground water may be a source of radiation exposure when used for irrigation, stock watering, food preparation, showering, or when incorporated into various industrial processes. Ground water contamination is also of concern to us because of potential adverse impacts upon ecosystems, particularly sensitive or endangered ecosystems.

Today's proposal utilizes the current MCLs, but the MCLs might change in the final rule. The Agency recognizes that the current MCLs are based upon the best scientific knowledge regarding the relationship between radiation exposure and risk that existed in 1975 when the MCLs were developed. Scientific understanding has evolved since 1975 and we are working to update the existing MCLs based upon a number of factors, including: the current understanding of the risk of developing a fatal cancer from exposure to radiation; pertinent risk management factors, e.g., information about treatment technologies and analytical methods; and applicable statutory requirements. Particularly relevant statutory requirements, in this context, are the requirements that MCLs be set as closely as feasible to the Maximum Contaminant Level Goal (MCLG) (SDWA section 1412(b)(4)(B)) and that revised drinking water regulations provide for equivalent or greater human health protection than the regulations they replace (SDWA section 1412(b)(9)). The Agency's preliminary efforts indicate that, for the radionuclides of concern at Yucca Mountain, the concentration values for those MCLs are probably not likely to change significantly. However, if those revisions to the MCLs are finalized prior to finalization of the part 197 standards, we plan to adopt those MCLs into the final part 197 standards. If part 197 is finalized first, the MCLs being proposed today would be maintained. We believe that this approach is necessary to provide stability for NRC and DOE in the licensing process. The uncertainty involved in not knowing when a change would occur and what form that change would take could delay the licensing proceeding. We request public comment upon this approach.

If you do not consider the proposed approach appropriate, please provide an alternative and rationale.

In July 1991, we issued the Strategy cited above in order to guide future EPA and State activities in ground water protection and cleanup. The Strategy presents an effective approach for protecting the Nation's ground water resources. Our policies, programs, and resource allocations reflect this approach. It guides EPA, State and local governments, and other parties in carrying out ground water protection programs. In addition, our Final Comprehensive State Ground-Water Protection Program Guidance" provides guidance to States for establishing a coordinated approach to their ground water protection.

The key element of our ground water protection strategy is the overall goal of preventing adverse effects upon human health and the environment by protecting the environmental integrity of the Nation's ground water resources. We believe that it is important to protect ground water to ensure that the Nation's currently used and potential USDWs are preserved for present and future generations. Also, we believe that it is important to protect ground water to ensure that where it interacts with surface water it does not interfere with the attainment of surface-water-quality standards. These standards are necessary to protect human health and the integrity of ecosystems.

Our Strategy also recognizes, however, that our efforts to protect ground water must take into consideration the use, value, and vulnerability of the resource, as well as social and economic values. In carrying out our programs, we use MCLs, established under the SDWA, as reference points for water-resource protection efforts when the ground water in question is a potential source of drinking water. Pursuant to section 1412 of the SDWA, we issued the National Primary Drinking Water Regulations for contaminants in drinking water which may cause an adverse effect upon the health of persons and which are known or anticipated to occur in public water systems (see 40 CFR parts 141 and 142). These regulations specify either MCLs or treatment techniques and contain "criteria and procedures to assure a supply of drinking water which dependably complies" with such MCLs (see SDWA § 1401). The relevant MCLs, for water containing less than 10,000 milligrams per liter (mg/L) of total dissolved solids (TDS) and assuming an ingestion rate of 2 L of water per day, are:

(1) 5 picocuries per liter (pCi/L) for combined radium-226 and radium-228;

(2) 15 pCi/L for gross alpha; and

(3) 4 mrem/yr for combined beta particle and photon radiation from man-made radionuclides.

We employ MCLs to protect ground water in numerous regulatory programs. This approach is reflected in our regulations pertaining to hazardous-waste disposal (40 CFR part 264), municipal-waste disposal (40 CFR parts 257 and 258), underground injection control (UIC) (40 CFR parts 144, 146, and 148), generic SNF, HLW, and transuranic radioactive waste disposal (40 CFR part 191), and uranium mill tailings disposal (40 CFR part 192). These Agency programs have demonstrated that such protection is scientifically and technically achievable, within the constraints applied in each of these regulations ("Progress In Ground Water Protection and Restoration," EPA 440/6-90-001).

Most ground water in the United States moves slowly, in the range of five to 50 feet per year. This means that a large amount of a contaminant can enter an aquifer and remain undetected until it affects a water well or surface-water body. Contaminants in ground water, unlike those in other environmental media like air or surface water, can move with relatively little mixing or dispersion, so concentrations can remain relatively high. Moreover, because ground water is below the Earth's surface and "out of sight," its contamination is far more difficult to monitor or remove than is contamination in air, surface water, or soil. These plumes of contaminants move slowly through aquifers and may be present for many years, sometimes for decades or longer, potentially making the resource unusable for extended periods of time. Because an individual plume may underlie only a small part of the land surface, it can be difficult to detect by aquiferwide or regional monitoring. In addition, for periods spanning thousands of years, monitoring is unlikely to continue, avoidance of the contamination may be difficult, and the area affected may become large. These factors are part of the reason that our policy emphasizes prevention of ground water pollution.

Regarding this rulemaking, NAS clearly identified the ground water pathway as one of the significant pathways of exposure in the vicinity of the Yucca Mountain site (NAS Report pp. 52 and 81). The NAS also recognized that ground water modeling for the Yucca Mountain site is complex, involving both fracture and matrix flow and, as a result, that there is uncertainty regarding which model or models to use in the analysis:

> Because of the fractured nature of the tuff aquifer below Yucca Mountain, some uncertainty exists regarding the appropriate mathematical and numerical models required to simulate advective transport....[E]ven with residual uncertainties, it should be possible to generate quantitative (possibly bounding) estimates of radionuclide travel times and spatial distributions and concentrations of plumes accessible to a potential critical group. (NAS Report p. 90)

The basis of NRC's determination of compliance with the ground-water protection standards will be DOE projections in the license application of potential future contaminant concentrations that will inevitably contain uncertainty. An important cause of uncertainty, as recognized above by NAS, is the choice of conceptual site models. To illustrate, the conceptual models used for Yucca Mountain can differ fundamentally, that is, water can be presumed to flow through either pores in the rock or conduits through the rock, such as discrete fractures or a network of fractures that may act as preferential pathways for faster ground water flow, or a combination of the two. To further complicate the situation, any of these flow scenarios, with the possible exception of flow through conduits, can occur at Yucca Mountain whether the rock is completely saturated with water or not.

We believe that adequate data and the choice of models will be critical to any compliance calculation or determination. The NAS has examined the use of ground-water flow and contaminant-transport models in regulatory applications ("Ground Water Models: Scientific and Regulatory Applications," 1990). In that report, NAS concluded that data inadequacy is an impediment to the use of unsaturated fracture flow models for Yucca Mountain. However, NAS noted that data inadequacy was also an impediment to using models that assume the pores in the rock are either saturated or unsaturated or that assume flow through fractures that are completely filled with water. However, despite the recognition of the importance of the choice of the site conceptual model, the Agency believes that the need for sufficient quantity, types, and quality of data to adequately analyze the site, because of its hydrogeologic complexity, is even more important. In other words, the complexity of the ground water flow system requires adequate site characterization to justify the choice of the conceptual flow model.

The choice of modeling approaches to address the ground water system in the area of Yucca Mountain, based upon the conceptual model of the site developed from site characterization activities, is important to characterize contaminant migration, particularly the mixing of water, contaminated with radionuclides from breached waste packages, with uncontaminated water. The extent of the dilution afforded by mixing contaminated water with other ground water moving through the rocks below the repository but above the water table and the dispersion of the plume of contamination within the saturated zone as the ground water system carries radionuclides downgradient are critical elements of the dose assessments.

At one end of a spectrum of approaches to modeling the site ground water system is the assumption that the system can be modeled based upon flow through pores over the area of total system assessments (tens of square kilometers). At the other extreme is the assumption that radionuclides are carried through fast-flow, fracture pathways in the unsaturated zone separately from uncontaminated ground water also passing through the repository footprint. Those radionuclides then are assumed to be carried through the saturated zone in fractures that allow little or no dispersion within, or mixing with, uncontaminated water in the saturated zone. This is essentially “pipe flow” from the repository to the receptor. Although the flow of ground water at the site is influenced strongly by fractures, which should be reflected in the models, we believe that it is unreasonable to assume that no mixing with uncontaminated ground water would occur along the radionuclide travel paths. We request comment upon this approach, including consideration of the practical limitations on characterizing the flow system over several or tens of square kilometers.

Our intention is to develop ground water protection standards that are implementable by NRC. In this regard, NAS indicated that quantitative estimates of ground water contamination should be possible (NAS Report p. 90). We are proposing to require DOE to project the level of radioactive contamination it expects to be in the representative volume of ground water. The representative volume could be calculated to be in any aquifer which contains less than 10,000 mg/L of TDS and is downgradient from Yucca Mountain. By proposing this method, we intend to avoid requiring DOE and NRC to project the contamination in a small, possibly unrepresentative amount of water since we believe that this is not practical (see the discussion of "representative volume of ground water" immediately below). For example, we do not intend that NRC must consider whether a few gallons of water in a single fracture would exceed the standards. Thus, we are proposing to allow use of a larger volume of water which must, on average, meet the standards. This larger volume, the “representative volume,” is discussed below.

Since the intended purpose of the engineered and natural barriers of the geologic repository is to contain radionuclides and minimize their movement into the general environment, we anticipate that radionuclide releases from the repository will not occur for long periods of time. With this in mind, we believe that ground water protection for the Yucca Mountain site should focus upon the protection of the ground water as a resource for future human use. It is the general premise of this proposal that the individual-protection standard would adequately protect those few current residents closest to the repository. The proposed ground water standards are directed to protecting the aquifer as a resource for current users, and a potential resource for larger numbers of future users either near the repository or for communities farther away comprised of as many as several hundred thousand people. To implement this conceptual approach and develop an approach for compliance determinations, we believe that the ground water standards currently used, the MCLs, should apply to public water supplies downgradient from the repository in aquifers at risk of contamination from repository releases. Applying the MCLs assures that the level of protection currently required for public water supplies elsewhere in the Nation is also maintained for future communities using the water supply downgradient from the Yucca Mountain repository.

To implement the standards in § 197.35, we are proposing that DOE use the concept of a "representative volume" of ground water in which DOE and NRC would project the concentration of radionuclides released from the Yucca Mountain disposal system for comparison against the MCLs. The representative volume will be the volume of water that would supply the annual water demands of a defined hypothetical community that could exist in the future at the point of compliance for the ground water protection standards. We believe that community size and water demand estimates should reflect the current, general lifestyles and demographics of the area, but not be rigidly constrained by current activities since any potential contamination would occur far into the future. In the area south of Yucca Mountain, the ground water is currently used for domestic purposes, commercial agriculture (for example, dairy cattle, feed crops, other crops, and fish farming), residential gardening, commercial, and municipal uses. The water resources, as reflected by estimates of current usage and aquifer yields, indicate that there is theoretically enough water to support communities of hundreds to thousands of people at the four alternative proposed locations for the point of compliance. This sets an upper bound on the size of the hypothetical community and its water demand. On the other hand, the SDWA defines the minimum size for a public water system as a system with 15 service connections or, regularly supplying at least 25 people.

For the four alternative proposed downgradient distances for the point of compliance (approximately 5, 18, 20, and 30 km from the repository), current populations vary from hundreds of persons around 30 km, to about 10 people residing at 18-20 km, to no residents at 5 km. Current projections of population growth in the area indicate increases at both the 20- and

30-km locations. Based upon current water usage, lifestyles, projections of population increases, and the potential number of people that could be supported by available ground water, there is a range of annual ground water volumes that could correspond to possible future public water system uses. While we believe that, ideally, the representative volume should be fully consistent with the protection objectives of the ground water protection strategy, we also recognize the unique features of this proposal. The extraordinary 10,000-year compliance period introduces unresolvable uncertainties that make this situation fundamentally different from the situations of clean-up or foreseeable, near-term potential contamination to which the strategy ordinarily applies. We therefore request comment upon a proposed representative ground water volume and upon possible alternatives for the size of the representative volume of ground water. These alternatives are based upon variations in possible lifestyles for residents downgradient from the repository and upon current and near-term projections of population growth and land use in the area.

The proposed representative volume is based upon a small farming community of 25 people and 255 acres of alfalfa cultivation, the current economic base in the Amargosa Valley. This approach assumes a community whose water needs include an agricultural component comparable to present water usage in the vicinity of the repository. The size of the average area of alfalfa cultivation, 255 acres, is based upon site-specific information for the nine alfalfa-growing operations which range in size from about 65 acres to about 800 acres. Using a water demand for alfalfa farming in Amargosa Valley of 5 acre-feet per acre per year, we estimate the water demand for the average operation to be 1275 acre-feet per year. As discussed below, it is appropriate to add 10 acre-feet per year for domestic uses resulting in 1285 acre-feet per year.

We request comment upon whether this approach is the most appropriate representative volume of ground water, or whether other values within the ranges discussed below are more appropriate. We believe that there may be significant technical, policy, or practical obstacles with the use of either very small or very large water volumes.

We considered using volumes of 10 and 120 acre-feet per year. Although the character of ground water movement in the saturated zone makes it progressively more difficult to model smaller volume flow, we are interested in comment upon the use of and whether, or how, it would be practical and feasible, using scientifically defensible methods, for the Commission to determine compliance with an alternative which specifies smaller representative volumes, such as 10 acre-feet and 120 acre-feet per year. A volume of 10 acre-feet would be representative of the annual water use of a non-farming family of four with average domestic water usage, including a garden. This is also the lower bound for the amount of water that would be used through 15 connections serving at least 25 persons in a public water supply, as defined in the SDWA. As mentioned in earlier discussions regarding the nature of ground water flow in fractured rocks, modeling the flow of ground water and the movement of contaminants involves significant uncertainties in the exact quantitative relationship between ground water movement in fractures versus its movement in the rock pore spaces. Modeling these processes, of necessity, requires simplifying assumptions and approximations that lower the level of confidence that can be attached to estimating contaminant concentrations in progressively smaller volumes of ground water. From our understanding of the complexity of the flow system at Yucca Mountain and the surrounding area, and the uncertainties involved in modeling it, a small representative volume such as 10 acre-feet would be difficult to model with a sufficient degree of certainty for regulatory confidence. The

Agency, of course, wants the size of the representative volume used in compliance calculations to be scientifically defensible in order to provide the public a reasonable certainty of their accuracy.

An annual water demand of 120 acre-feet assumes a community of 150 persons and is based upon current water use data for the area. This population estimate is based upon recent population increases in the area and 20-year projections of land use at the 20-km location, as described in county planning documents. In such a scenario, it would be important for commenters to look at whether it is appropriate to assume this community would have an agriculture component, or whether a primarily residential community is more appropriate.

We also considered using a volume of 4,000 acre-feet which would be representative of the estimated perennial yield of the Jackass Flats hydrographic sub-basin in which the proposed Yucca Mountain repository is located. This volume represents the annual sustainable quantity of water which could be removed from this sub-basin without significantly decreasing the subsequent water yield and quality in the future. This volume is not directly linked to any specific use, but rather is included as representative of the volume of the water resource for potential future, large-scale, sustainable ground water use.

As already stated, we believe that there may be significant technical, policy, or practical obstacles that preclude the use of such a large volume. Releases from the repository will migrate downward and into the saturated zone where the contaminated ground water will move generally southward. The Jackass Flats sub-basin covers a large area, most of which is east of the repository site and not in the path of ground water flow from the repository. The Agency did not include this alternative in the rule since the use of 4,000 acre-feet would result in a contaminant estimate based upon dilution by a large volume of unaffected water. We are requesting comment upon the use of 4,000 acre-feet as the basis for the Commission to determine compliance with an alternative which specifies this volume as representative of the ground water resource.

To implement these options, the Department would project the radionuclide concentration in the representative volume or the resultant doses, for the option selected, and compare them against the appropriate MCLs. For these calculations, the movement of radionuclides released from the repository must be calculated as they move downgradient toward the compliance point. For the purpose of demonstrating compliance with the ground water protection standards, we intend for DOE and NRC to use the performance assessments to determine compliance with the individual-protection standard to calculate the concentration of radionuclides in the ground water.

There are two basic approaches between which DOE must choose for calculating the concentrations of radionuclides at the point of compliance. The Department may perform this analysis by determining how much contamination is in: (1) a “well-capture zone”; or (2) a “slice of the plume.” (These approaches are explained immediately below.) For either approach, the volume of water used in the calculations is equal to the representative volume, i.e., the annual water demand for the proposed future group using the ground water.

The “well-capture zone” is the volume from which a water supply well, pumping at a defined rate, is withdrawing water from an aquifer. The dimensions of the well-capture zone are determined by the pumping rate in combination with aquifer characteristics assumed for calculations, such as hydraulic conductivity, gradient, and the screened interval. If this approach is used, DOE must assume that the:

(1) well has characteristics consistent with public water supply wells in Amargosa Valley, for example, well bore size and length of the screened interval;

(2) screened interval is centered at the highest concentration in the plume of contamination at the point of compliance; and

(3) pumping rate is set to produce an annual withdrawal equal to the representative volume.

To include an appropriate measure of conservatism in the compliance calculations for the well withdrawal approach, we are proposing that, for the purpose of the analysis, DOE should assume that the community water demand would be supplied from one pumping well located in the center of any projected plume of contamination originating in the repository. Conservatism is achieved by requiring that the entire water demand is withdrawn from one well intercepting the center of the plume of contamination so that the highest radionuclide concentrations in the plume are included in the volume used for the compliance calculations.

The "slice of the plume" is a cross-section of the plume of contamination centered at the point of compliance with sufficient thickness parallel to the prevalent flow of the plume such that it contains the representative volume. If DOE uses this approach, it must:

(1) propose to NRC, for its approval, where the edge of the plume of contamination occurs, for example, where the concentration of radionuclides reaches 0.1% of the level of the highest concentration at the point of compliance;

(2) assume that the slice of the plume is perpendicular to the prevalent direction of flow of the aquifer; and

(3) set the volume of ground water contained within the slice of the plume equal to the representative volume.

In both alternatives, we are proposing that DOE must determine the physical dimensions and orientation of the representative volume during the licensing process, subject to approval by the Commission. Factors that would go into determining the orientation of the representative volume would include hydrologic characteristics of the aquifer and the well.

Under our proposal, the Department must demonstrate compliance with the proposed ground water protection standards (§ 197.35) assuming undisturbed performance of the disposal system. The term "undisturbed performance" means that human intrusion or the occurrence of unlikely, disruptive, natural processes and events do not disturb the disposal system. This approach recognizes that human behavior is difficult to predict and, if human intrusion occurs, that individuals may be exposed to radiation doses that would be more attributable to human actions than to the quality of repository siting and design (NAS Report p. 11). The requirement that DOE project performance for comparison with the ground water protection standards based upon undisturbed-performance scenarios is consistent with our generally applicable standards for SNF, HLW, and transuranic waste in 40 CFR part 191 (58 FR 66402, December 20, 1993; 50 FR 38073 and 38078, September 19, 1985).

We also are proposing to require that DOE combine certain estimated releases from the Yucca Mountain disposal system with the pre-existing naturally occurring or man-made radionuclides to determine the concentration in the representative volume (see Table 1 in the What should the Level of Protection Be? section earlier in this notice for particular cases). This means that the releases of radionuclides from radioactive material in the Yucca Mountain disposal system must not be allowed to cause the projected level of radioactivity at the point of compliance to exceed the limits in § 197.35 with reasonable expectation.

We request public comment upon these approaches. Comments also are requested upon whether it is desirable and appropriate for us to provide more quantitative requirements for the proposed representative volume in the final standards. If so, please provide specifics.

III.F.1. Is the Storage or Disposal of Radioactive Material in the Yucca Mountain Repository Underground Injection?

We first addressed the issue of whether the disposal of radioactive waste in geologic repositories might be considered a form of underground injection in a rulemaking to amend 40 CFR part 191. In the preamble to the final amendments (58 FR 66398), we stated that it was unnecessary to address whether the disposal of radioactive waste in a geologic repository covered under 40 CFR part 191 constitutes underground injection under the SDWA since the ground water protection requirements in 40 CFR part 191 conformed with the MCLs. We also noted that in NRDC v. EPA, 824 F.2d at 1270-71, the First Circuit Court of Appeals itself did not resolve the underground injection issue. The Court stated only that disposal in geologic repositories would "likely" constitute underground injection. Also, in the preamble to the 40 CFR part 191 amendments, we reviewed the SDWA, its legislative history, and the regulations governing the UIC program. We concluded that the underground disposal of containerized radioactive waste in geologic repositories subject to 40 CFR part 191 does not constitute underground injection within the meaning of the SDWA or our regulations governing the UIC program (58 FR 66398, 66408-66411, December 20, 1993). Similarly, in the present rulemaking, we propose to find that the storage or disposal of containerized radioactive waste in Yucca Mountain does not constitute underground injection.

Section 1421 of the SDWA defines "underground injection" as "the subsurface emplacement of fluids by well injection." 42 U.S.C. 300h(d)(1). The statute defines neither "fluids" nor "well injection." Moreover, neither the statute nor the legislative history directly addresses whether the underground storage or disposal of containerized radioactive waste constitutes the "subsurface emplacement of fluids by well injection." Even though the legislative history states, "[t]he definition of 'underground injection' is intended to be broad enough to cover any contaminant which may be put below ground level and which flows or moves, whether the contaminant is in semi-solid, liquid, sludge, or any other form or state," (H.R. Rep. No. 1185, 93d Cong., 2d Sess. 31 (1974)), it does not specifically address whether the underground storage or disposal of containerized radioactive waste in a geologic repository, such as Yucca Mountain, constitutes the "subsurface emplacement of fluids by well injection."

In this rulemaking, we are proposing to conclude that the underground storage or disposal of containerized radioactive waste in the Yucca Mountain repository does not constitute underground injection both because the materials to be emplaced are not "fluids" and because the mode of emplacement of these materials is not "well injection." We do not consider the type of containerized radioactive wastes covered under today's proposal to be "fluids." Instead, DOE plans for the wastes to consist entirely of solid materials and to be enclosed in thick metal waste packages. We do not believe that the SDWA's reference to "subsurface emplacement of fluids" was intended to address the subsurface storage or disposal of solid, containerized materials. As noted above, neither the statute nor the legislative history specifically address the subsurface emplacement of containerized materials or solids. On the other hand, the legislative history does address the injection of liquid materials that flow or move at the time they are emplaced into the ground. For example, in floor debate, Sen. Domenici stated that "the [UIC] regulations would cover all types of injection wells from industrial and nuclear disposal wells, oil and gas injection wells, solution mining wells or any hole in the ground designed for the purpose of injecting water or other fluids below the surface" (see 126 Cong. Rec. 30189, November 19, 1980, remarks of Sen. Domenici). Indeed, in amending the SDWA in 1985, Congress stated "underground injection is the process of forcing liquids underground through a well." H.R. Rep. No. 168, 99th Cong., 1st Sess. 30 (1985). Moreover, it is clear from the legislative history of the SDWA that Congress intended to ratify EPA's policy regarding deep-well injection contained in Administrator's Decision Statement #5, entitled "Subsurface Emplacement of Fluids," (39 FR 12922, April 2, 1974, H.R. Rep. No. 1185, 93rd Cong., 2d Sess. 31 - 32 (1974)). Administrator's Decision Statement #5 contains parameters for well injection including, among other things, data requirements for volume, rate, and injection pressure of the fluid; degree of fluid saturation; and formation and fluid pressure (39 FR 12923, April 9, 1974). Like the legislative history itself, the policy does not mention the subsurface emplacement of containerized radioactive wastes, but it does address the injection of noncontainerized liquids as an object of regulatory concern.

The legislative history of the SDWA indicates that Congress was concerned about contamination of ground water from a variety of sources of noncontainerized liquids and sludges. Quoting from a U.S. Department of Health, Education and Welfare report entitled "Human Health and the Environment--Some Research Needs," Representative Rogers noted in floor debate that ground water pollution was rapidly increasing from sources including "...waste water sludges and effluents...mine drainage, subsurface disposal of oil-field brines, seepage from septic tanks and storage transmission facilities, and individual on-site waste-water disposal systems." (123 Cong. Rec. 22460 (July 12, 1977)). Later in 1985, Congress made clear its intent that there would be early detection of fluid migration into or in the direction of a USDW (H.R. Rep. No.

168, 99th Cong., 1st Sess. 30 (1985)). Again, there is no mention that Congress intended that the SDWA cover the subsurface emplacement of containerized radioactive wastes.

Reflecting this statutory approach, our UIC regulations similarly do not treat containerized radioactive wastes as fluids or liquids for the purpose of control under the UIC program. Our regulations at 40 CFR 146.3 define "fluid" as "material or substance which flows or moves whether in a semisolid, liquid, sludge, gas, or any other form or state." In adopting this regulatory definition of fluid, we did not consider the emplacement of containerized radioactive wastes into geologic repositories to be fluids subject to the UIC regulations. There is no mention of this activity in the preambles to the proposed or final UIC regulations. On the contrary, the fluids regulated by our UIC program include: (1) brines from oil and gas production; (2) hazardous and industrial waste waters; (3) liquid hydrocarbons (gasoline, crude petroleum, and others); (4) solution mining fluids from uranium, sulfur, and salt solution mining; and (5) sewage and treated effluent (40 CFR 144.6). All of these materials can flow or move at the time they are emplaced into the ground. There is no indication of any intention to cover containerized materials as fluids under the UIC regulations.

Finally, we have never interpreted our UIC regulations to include the subsurface emplacement of containerized wastes or solid materials that do not flow or move. As explained in greater detail below, we have stated instead that placement of containerized hazardous waste in geologic repositories such as underground salt formations, mines, or caves, is regulated under Subtitle C of the RCRA hazardous waste program. Subtitle D of RCRA regulates the disposal of containerized, nonhazardous wastes pursuant to the regulatory provisions at 40 CFR 257.1. Today's proposed standards for Yucca Mountain regulate the emplacement and disposal of containerized radioactive wastes including SNF and HLW.

In NRDC v. EPA, 824 F.2d 1258, the First Circuit was concerned that radiation itself might be considered a fluid within the meaning of the SDWA and EPA's UIC regulations (40 CFR 146.3). We believe that radiation itself does not meet the UIC regulatory or statutory definition of "fluid." Radioactivity is a specific characteristic of the radionuclides in the waste but does not define the form of the waste. Also, radioactivity results in the emission of ionizing radiation in the form of electromagnetic energy or subatomic particles. Electromagnetic radiation is a form of energy, not a "material or substance." Hence, it is not a "fluid." Subatomic particles, such as alpha and beta particles, will be absorbed in either the waste or the container and, therefore, not travel beyond the container, or will travel very short distances, perhaps a few inches. In any event, as set forth above, we believe that since the activity at the Yucca Mountain repository will consist of the emplacement of containers of radioactive wastes underground, this activity is emplacement of solid materials, not "fluids." Even though these materials might eventually disintegrate or dissolve and release some radiation, liquids, or gases, the activity in question still consists of emplacement of containers and solid materials that will not flow or move at the time of emplacement underground.

Moreover, we do not consider the emplacement into the Yucca Mountain repository of containerized and solid wastes that do not flow or move to be subsurface emplacement "by well injection." At the Yucca Mountain repository as currently conceived, a rail car will be used to carry the containerized waste into the repository. The waste containers then will be emplaced in drifts mined into the geologic formation. Once enough containers are accumulated, each drift will be closed. Closure of the disposal system will occur when all of the openings into the repository have been backfilled and all entrance ramps sealed.

Our UIC regulations define "well injection" as "subsurface emplacement of fluids through a bored, drilled or driven well; or through a dug well, where the depth of the dug well is greater than the largest surface dimension" (40 CFR 146.3). The regulations define a "well" as "a bored, drilled or driven shaft, or a dug hole, whose depth is greater than the largest surface dimension" (Id.). Although movement of the materials underground in the Yucca Mountain repository will involve waste handling, it will be drifts, that is, tunnels, through which containerized solid materials are transported and emplaced, not "wells" into which fluids are being "injected" within the meaning and intent of the SDWA or our UIC regulations. In addition, the overall configuration of the repository is far different from that of a "drilled," "driven," or "dug" injection well.

We noted in the preamble to the proposed UIC rules setting forth the definitions of "well" and "well injection" that the definitions cover not only "conventional" deep wells, but also drilled, bored, and driven wells. Dug wells and non-residential septic tanks also fall under the term. We further stated, however, that "although the definition is broad, it is not without limitation." (44 FR 23738, 23740, April 20, 1979) For example, we stated that the term does not cover simple depressions in the land or single-family domestic cesspools or septic systems, nor does it cover surface impoundments (Id.). Although we had been concerned initially about whether the UIC regulations should impose conditions upon surface impoundments, generally referred to as "pits, ponds, and lagoons," since they pose a threat to ground water, we noted that standards to control such contamination are under the RCRA hazardous-waste management program (44 FR 23740, April 20, 1979). Thus, we recognized that there are some disposal practices that might contaminate ground water that would not be covered under the UIC program.

Similarly, we do not believe that the UIC program should cover emplacement of containerized waste by way of a drift. Such emplacement is in no way similar to the pressurized or gravity-driven flow of fluids, liquids, or sludges injected into a well that has been the traditional focus of the UIC program (for example, 41 FR 36726, 36732, August 31, 1976). Even Class-V wells, a general category of injection wells, are not used for the disposal of containerized waste. Class V covers the subsurface emplacement of fluids, usually by gravity-driven flow, into the injection well. Although Class-V wells include some types of wells that traditionally might not be thought of as injection wells, for example, septic systems, all of the well types involve the emplacement of noncontainerized fluids into drilled, bored, dug, or driven wells, typically through gravity-driven flow rather than pressurized flow.

We specifically addressed the status of containerized waste under RCRA and SDWA in the preamble to the final rule promulgating standards for miscellaneous units used for the disposal of hazardous wastes under subpart X of the RCRA regulations (40 CFR part 264). In the preamble to the final rule, we stated: “Placement of containerized hazardous waste or bulk non-liquid hazardous waste in geologic repositories such as underground salt formations, mines, or caves, either for the purpose of disposal or long-term retrievable storage, is included under subpart X” (52 FR 46946, 46952, December 10, 1987).

We promulgated the subpart X regulations to address hazardous-waste management technologies not covered under 40 CFR part 264 (RCRA regulations for the disposal of hazardous waste) or 40 CFR part 146 (UIC program technical criteria and standards). As we indicated in the preamble to the subpart X regulations, the 40 CFR part 146 technical standards do not address practices other than the injection of noncontainerized liquids, slurries, and sludges, and do not fully address some potential disposal or storage practices that may fall under our regulatory definition of well injection (52 FR 46946, 46953, December 10, 1987). In the subpart X rule, we provided that, to the extent that miscellaneous disposal practices subject to subpart X might be underground injection, a subpart X permit would constitute a UIC permit for well injection of hazardous waste for which current 40 CFR part 146 technical standards are not generally appropriate. We stated, however, that we were not "specifying that these miscellaneous management practices constitute underground injection" (Id.).

Thus, we have never expressed an intent that the disposal of containerized waste, including containerized radioactive waste, in geologic repositories is an activity covered by the UIC program. Instead, injection wells have been described as “facilities [within] which wastes, in a fluid (usually liquid) state, are injected into the land under a pressure head greater than the pressure head of the ground water into or above which they are injected for the purpose of disposal. Discharge to the ground water is either direct or by direct seepage of leachate from the well outlet (46 FR 11126, 11137-38, February 5, 1981).

Moreover, we have never intended for the regulatory criteria and standards applicable to underground injection, contained in 40 CFR parts 144 and 146, to apply to a geologic repository such as Yucca Mountain. The concepts of area of review, pressure buildup and pressure monitoring, restrictions upon injection pressure, other operating requirements, and mechanical-integrity testing of injection wells, that are included in the 40 CFR part 146 regulations, are meaningless as applied to Yucca Mountain. Further, as noted above, the Yucca Mountain disposal system will have mined containment areas in which humans operate mechanical equipment to emplace waste packaged in containers surrounded by both engineered and natural barriers designed to isolate such waste from the environment. The UIC regulations are directed at injection of fluids by pressure or gravity flow where they are then in direct contact with the natural, underground media; this activity is far different, from an engineering perspective, than the subsurface emplacement of containerized wastes planned for Yucca Mountain.

Finally, as explained below, we are proposing specific ground water protection standards, in addition to other public health and safety standards, to protect ground water resources in the vicinity of Yucca Mountain. We believe these standards are adequate to protect public health and the environment from the radiation exposure resulting from releases following the emplacement of these containerized radioactive wastes into the Yucca Mountain disposal system. Thus, it is not necessary to expand the scope of the UIC program to cover this activity.

<u>III.F.2. Does the Class-IV Well Ban apply?</u>

Today's action provides protection, with one possible exception, substantively similar to the SDWA through the proposed adoption of the MCLs to protect ground water resources in the vicinity of Yucca Mountain (proposed § 197.35). The possible exception relates to the provision of 40 CFR 144.13 banning "Class IV" injection wells. As defined in 40 CFR 144.6(d), such wells include those which dispose of radioactive waste into or above a formation which contains a USDW within one-quarter (¼) mile of the well. In the preamble to the amendments to 40 CFR part 191 (58 FR 66398, 66410, December 20, 1993), we said we would further consider the Class-IV well-ban issue in the context of the Yucca Mountain rulemaking. We have done so and are proposing in this rulemaking not to apply the Class-IV injection-well ban to the Yucca Mountain repository. Our position is that this is appropriate in light of the statutory and regulatory provisions, discussed above, relating to “underground injection” and the differences in the purposes of the UIC program and the authority delegated to us under the EnPA to establish public health and safety standards for Yucca Mountain.

The UIC regulations mandate minimum requirements for State programs to prevent underground injection which endangers USDWs, while the 40 CFR part 197 standards proposed for Yucca Mountain are directed toward protecting ground water in the accessible environment in the vicinity of the Yucca Mountain site and establish requirements for performance of the Yucca Mountain disposal system. As discussed below, we believe that the proposed standards for the Yucca Mountain disposal system achieve public health and environmental protections comparable to those of the UIC program. Moreover, as discussed above, we do not believe that the emplacement of radioactive waste in the Yucca Mountain disposal system is a form of underground injection. Therefore, we are proposing to find that the Class-IV well ban does not apply to, and is not needed, in the case of the Yucca Mountain disposal system.

It is important to emphasize that our proposed decision not to apply the Class-IV well ban to Yucca Mountain does not affect other disposal systems that dispose of hazardous or radioactive waste into or above a formation which, within one-quarter (¼) mile of the disposal system, contains a USDW. We are basing today's proposal upon site- and facility-specific characteristics of the Yucca Mountain repository, and today’s proposal is limited to the Yucca Mountain repository.

The Class-IV well ban is part of the UIC program and is recognized in section 3020 of RCRA. As explained previously, the UIC program addresses "well injection" in the common-sense meaning of that term. In contrast, the proposed 40 CFR part 197 regulations address emplacement of radioactive wastes into a uniquely designed and utilized facility. The Yucca Mountain disposal system is planned to be subjected to extremely sophisticated site characterization, design, engineering, containerization, and operational requirements. Given such intense scrutiny, applying a blunt instrument akin to the Class-IV well ban as a siting prohibition appears to be both unnecessarily restrictive and a poor substitute for more sophisticated site characterization studies that may preclude siting of a disposal facility for reasons other than those embodied in the Class-IV restriction. Further, if Congress intended that the Yucca Mountain disposal system be subject to and summarily precluded by the Class-IV well ban, we seriously question whether Congress would have specifically directed us, under the EnPA, to establish public health and safety standards for Yucca Mountain.

Previously, we explained our proposed conclusion that emplacement of radioactive material into the Yucca Mountain disposal system is not underground injection. The materials to be disposed are solid, containerized radioactive wastes emplaced in a mined containment system in which humans operate heavy mechanical equipment. Such emplacement and such materials do not fall under the intent or meaning of the UIC concepts or programs, or more specifically, the Class-IV well ban at 40 CFR 144.13, but are judged more appropriately by the standards mandated by Congress under the EnPA specifically for Yucca Mountain. Further, the ground water protection alternatives presented in today's proposal provide protections very comparable to those under the UIC program.

Taken together, we believe these distinctions are sufficient to justify nonapplicability of the Class-IV well ban under the SDWA. We request comment upon our position that application of the UIC Class-IV well ban is neither legally required nor appropriate for the Yucca Mountain disposal system. Further, we will not address in this rulemaking the relevance of the Class-IV well ban to underground repositories generally.

III.F.3. Which Ground Water should be Protected?

Although we propose to find that the Yucca Mountain disposal system is not a form of underground injection in the context of the SDWA, we nevertheless consider the ground water protection principles embodied in the SDWA to be important. Therefore, while not applying all aspects of the SDWA, we are proposing ground water protection standards consistent with the levels of the radionuclide MCLs.

We request public comment upon the proposal and the other approaches, described below, that are designed to protect ground water resources in the vicinity of the repository. We are concerned that ground water resources in the vicinity of Yucca Mountain receive adequate protection from radioactive contamination. The primary purpose of our proposed standards is to prevent contamination of drinking-water resources. (Since the proposed compliance period is 10,000 years after disposal, references to levels of contamination mean those levels projected to exist at specific future times, unless otherwise noted. However, these projections will be made at the time of licensing.) This prevents placing the burden upon future generations to decontaminate that water by implementing expensive clean-up or treatment procedures. We believe it is prudent to protect drinking water from contamination through prevention rather than to rely upon clean-up afterwards. The cost to remediate the effects of radionuclides released from a geologic disposal system, such as Yucca Mountain, could far exceed the costs typically associated with near-surface Superfund sites. Moreover, absent this protection through prevention, the disposal system itself could become subject to clean-up by future generations. Thus, our proposed ground water protection standards stress pollution prevention and provide protection from contamination of sources of drinking water containing up to 10,000 mg/L of TDS. We emphasize that all ground water pathways, including drinking water, are also covered under the proposed individual-protection standard (§ 197.20).

The definition of USDW received extensive discussion in the legislative history of the SDWA as reflected in the report of the House Committee on Interstate and Foreign Commerce. To guide the Agency, the Committee Report suggested inclusion of aquifers with fewer than 10,000 mg/L of TDS (H.R. Rep. No. 1185, 93d Cong., 2d Sess. 32, 1974). We have reviewed the current information on the use of aquifers for drinking water which contain high levels of TDS. This review found that ground water containing up to 3,000 mg/L of TDS that is treated is in widespread use in the U.S. In the Yucca Mountain vicinity, with few exceptions (one being the Franklin Playa area), ground water contains less than 1,000 mg/L of TDS. Our review also found that ground water elsewhere in the Nation, containing as much as 9,000 mg/L of TDS, currently supplies public water systems. Based upon this review and the legislative history of the SDWA, we are proposing that it is reasonable to protect the aquifers potentially affected by releases from the Yucca Mountain disposal system. Therefore, the provisions found in proposed § 197.35 would apply to all aquifers, or their portions, containing less than 10,000 mg/L of TDS. The proposed definitions associated with § 197.35 are taken directly from our UIC regulations found in 40 CFR parts 144-146.

III.F.4. How Far into the Future should Compliance be projected?

We are proposing a 10,000-year compliance period for ground water protection. This is consistent with the 10,000-year compliance period we are proposing for the individual-protection standard and, therefore, provides internal consistency within the proposed standards. This time period would also make the ground water protection compliance period consistent with 40 CFR part 191. Consistency also is achieved with regulations covering long-lived chemically hazardous wastes which present potential health risks similar to those from radioactive waste.

In addition to trying to achieve consistency with our other hazardous and radioactive-waste programs, we are concerned about the uncertainty associated with projecting radiation doses over periods longer than 10,000 years. The NAS indicated that beyond 10,000 years uncertainty will likely continue to increase (NAS Report p. 72). As a result, it will become increasingly difficult to discern a difference between the radiation dose from drinking water containing radionuclides (limited by the MCLs) and the total dose arriving through all pathways (which is limited by the individual-protection standard).

In fact, we considered incorporating a compliance period of time-to-peak concentration within the geologic stability of the site. However, this approach may be unworkable and duplicative of the requirements already promulgated in the MCLs. The current MCLs for radionuclides are expressed both in terms of radiation dose and concentration. For man-made beta and photon emitters, the MCL is a dose limit of 4 mrem/yr, with specific instructions for determining radionuclide-specific concentrations corresponding to that dose (40 CFR part 141.16(b)). For radium-226 (^{226}Ra) and ^{228}Ra combined, the MCL is a concentration level of 5 pCi/L of water, while for gross-alpha activity (including ^{226}Ra but excluding radon and uranium), the MCL is a concentration level of 15 pCi/L (40 CFR 141.15(a) and 141.15(b), respectively).

The Yucca Mountain disposal system will contain all of these types of radionuclides. To express a regulatory limit for ground water protection in terms of a single limit on peak concentration may be impractical because of the separate, multiple, and distinct MCLs established by regulation. Although the gross-alpha limit is set at 15 pCi/L to limit lifetime cancer risk to about 1×10^{-4}, the concentrations of specific alpha-emitting radionuclides corresponding to this risk level may vary widely. For various thorium isotopes, concentrations of 50 to 125 pCi/L are equivalent to this risk, while for either neptunium-237 or plutonium-238, a concentration of 7 pCi/L corresponds to a lifetime cancer risk of 1×10^{-4} (56 FR 33050, 33121, July 18, 1991). To develop a limit on the peak concentration for each radionuclide would be unwieldy, because of the large number of radionuclides involved. To establish a single, overall, limiting peak concentration applicable to all radionuclides would be, at best, an approximation of the public-health protection already embodied in the MCLs. For these reasons, we are concerned that expressing ground water protection requirements in terms of a single, peak concentration or numerous radionuclide-specific limits is not appropriate.

We request comment upon our proposal to impose the ground water protection standards during the first 10,000 years following disposal and whether we should, instead, adopt a compliance period of time-to-peak concentration (see the <u>How Far into the Future should Compliance be projected?</u> section earlier in this notice for a discussion of time-to-peak-dose compliance period which is the basis of this concept). Commenters recommending the time-to-peak-concentration approach should address our concerns, particularly those related to implementability, as expressed above.

<u>III.F.5. How will the Point of Compliance be Identified?</u>

To provide a basis for determining projected compliance with § 197.35, it is necessary to establish a geographic location where DOE must project the concentrations of radionuclides in the ground water over the compliance period. We refer to this location as the “point of compliance.”

In this section, we will discuss two alternative approaches for determining the location of the point of compliance. In the final rule, we will specify the location to be used by NRC and DOE as the point of compliance. One approach (used in Alternatives 1 and 4) would establish the maximum size for an area around the repository (that is, a “controlled area”) which would be exempt from the ground water protection standards. In demonstrating compliance, the Department would choose the point on the area’s boundary located above the primary ground water flow pathway and where the highest concentrations of radionuclides are expected to be found. Under the second approach (used in Alternatives 2 and 3), we would specify a specific geographic location where we believe the primary ground water flow pathway and the highest concentrations of radionuclides will be. If the Department’s improved knowledge of ground water flow direction changes the expected location of the highest concentrations of radionuclides, DOE must propose that location to NRC as an alternative point of compliance. This new point of compliance, however, must be at the same distance from the repository as the originally promulgated point of compliance. As discussed below, DOE must obtain the approval of the Commission prior to using the alternative point for demonstrating compliance.

Under the “controlled area” approach of Alternatives 1 and 4, the standards would designate an area within which DOE would not have to demonstrate compliance with the ground water protection standards. These standards would apply outside of that area. Under this approach, we are proposing that the Department would have to determine the point on the boundary of the controlled area where the highest projected concentrations of radionuclides will occur. That location would become the point of compliance. In effect, a certain volume of the geologic medium would be dedicated to delaying or keeping releases from the waste within the controlled area and away from the accessible environment. We adopted a generic definition of controlled area in 40 CFR part 191. The definition of controlled area for this rulemaking could take into account unique features in the vicinity of the Yucca Mountain site or we could adopt the definition from part 191. An alternative for each definition is presented and discussed below.

Not applying the ground water protection standards inside a controlled area is consistent with the approach in 40 CFR Part 191 in which the natural geologic barriers surrounding radioactive-waste repositories are a part of the disposal system and may be dedicated for this purpose (50 FR 38066, 38077, September 19, 1985). We implemented this concept in 40 CFR part 191 by requiring compliance with ground water standards outside of the controlled area. This concept was upheld by the First Circuit in NRDC v. EPA, 824 F.2d at 1272-73 & 1277-79. The court reasoned that allowing for contamination of some area surrounding a geologic repository was consistent with the site-selection provisions of the NWPA and that Congress expected DOE to rely upon geologic barriers and, therefore, "knew of the inevitability of some contamination of ground water in the immediate area of the stored waste." NRDC v. EPA, 824 F.2d at 1278.

For Yucca Mountain, the EnPA also generally follows the approach of dedicating some portion of the surrounding geology for containment and requiring compliance in the accessible environment outside of such an area. For example, section 801(a)(1) of the EnPA specifically uses the term "accessible environment" (that is, outside of the controlled area) when calling for us to prescribe standards for “releases to the accessible environment from radioactive materials stored or disposed of in the repository.” The EnPA also specifically incorporates the definition from 40

CFR part 191 in its direction to NAS to address whether a health-based standard based upon doses to individual members of the public “from releases to the accessible environment (as that term is defined in the regulations in subpart B of part 191 of title 40, Code of Federal Regulations, as in effect on November 18, 1985)” will provide a reasonable standard for protection of the general public.

The second approach (Alternatives 2 and 3) for establishing a point of compliance is the identification of a specific location where DOE must project the concentration of radionuclides. Rather than designating a "controlled area," under this approach we would specify a specific point as the point of compliance. This approach relies upon current knowledge of the ground water flow system in the region around Yucca Mountain with a realization that more information may be available to DOE and NRC at the time of licensing. Therefore, if this approach is the one we adopt in the final standard, it is important to explain our current understanding of ground water flow in the area and to establish a mechanism which allows flexibility for selecting an alternative point of compliance during licensing if the current conceptual model proves no longer valid at the time of licensing. Despite the fact that a particular point would be designated, please note that this approach would allow radioactive contamination in the path of the plume of contamination between the repository footprint and the point of compliance. In fact, the intervening area could contain ground water which is contaminated above the ground water protection standards. However, with this approach, those standards could not be exceeded at or beyond the point of compliance during the proposed 10,000-year compliance period.

Our understanding, based upon current knowledge, of the flow of ground water passing under Yucca Mountain is as follows. The general direction of ground water movement in the aquifers under Yucca Mountain is south and southwest. The major aquifers along the flow path are in tuff, alluvium, and, underlying both of these, much deeper carbonate rocks. At the edge of the repository, even the tuff aquifer is relatively (several hundred meters) deep. It gets closer to the surface as it moves toward its natural discharge points. Potential releases of radionuclides from the engineered barrier system into the surrounding rocks would be highly directional and would reflect the orientation of fractures, rock unit contacts, and ground water flow in the area downgradient from Yucca Mountain. Directly under the repository, we anticipate that any waterborne releases of radionuclides will move through the unsaturated zone and downward into the tuff aquifer, in an easterly direction, between layers of rocks which slant to the east, and then horizontally. The layer of tuff gradually thins proceeding south (downgradient) from Yucca Mountain. As the tuff thins, the overlying alluvium becomes thicker until the tuff disappears and the water in the aquifer moves into the alluvium to become the "alluvial aquifer." Along the flow path, there might be movement of water between the carbonate aquifer and either the tuff or alluvial aquifers. If there is significant upward flow from the carbonate aquifer, contamination in overlying aquifers could be diluted. It is generally believed, however, that any such flow would not significantly affect the concentration of radionuclides in the overlying aquifers. Conversely, downward movement of ground water from the tuff aquifer could contaminate the carbonate aquifer. Today, most of the water for human use is withdrawn between 20 and 30 km away from the repository footprint (that is, at Lathrop Wells and farther south through the Town of Amargosa Valley) where it is more easily and economically accessed for agricultural use and human consumption. It is likely that water within the alluvial aquifer is the source of this water.

Another basis of our understanding is the historical record of water use in the region. That record indicates that significant, long-term human habitation has not occurred in the southwestern area of the NTS, or for that matter anywhere in the vicinity of Yucca Mountain, except where ground water is very easily accessible, for example, in Ash Meadows. This observation coincides with current practice whereby the number of wells generally decreases relative to the greater depth to ground water. The difficulty in accessing ground water in the tuff aquifer in the near vicinity of Yucca Mountain is made more difficult by the rough terrain, the relative hardness of the tuff formations containing the aquifer, and the great depth to ground water there. As described earlier, the ground water flow from under Yucca Mountain is thought to be generally south and southwest. In those directions, the ground water gets progressively closer to the Earth’s surface the farther away it gets from Yucca Mountain until it is thought to discharge to surface areas 30-40 km away (the southern boundary of NTS is about 18 km from Yucca Mountain). This means that access into the upper aquifer is easier at increasing distance from Yucca Mountain. It should also be pointed out, the Yucca Mountain site is on several Federally controlled areas of land, i.e., the Nellis Test Range, NTS, and Bureau of Land Management land. In these areas, the U.S. government is the senior appropriator and holds water rights, i.e., water is appropriated for beneficial use by and for the U.S. government.

Because of DOE's ongoing site characterization studies, it is possible that, at the time of licensing, data not now available will reveal important inaccuracies in the preceding conception of ground water flow. In proposing Alternatives 2 and 3 (see discussion below), we intend that the location of the point of compliance will be where the highest concentrations of radionuclides within the plume are projected by DOE and NRC to be. We believe, based upon current information, that the locations specified for the proposed alternative points of compliance in

Alternatives 2 and 3 are likely to include such concentrations.

However, if DOE and NRC determine that the direction of ground water flow or location of the highest concentration is different than now believed because new knowledge is available at the time of licensing, we propose to require the Department to propose to the Commission the location where the highest concentration is projected to be. Any such new point of compliance would replace the one we specify in the final rule only if it is at the same distance from the repository as the original point of compliance and is approved by the Commission. It may be moved only to account for new information regarding flow-direction or the location of the highest concentration. We believe such flexibility will enhance the quality of NRC's licensing decision and will provide greater protection of public health and the environment by taking into account the latest available information. We request comment upon this approach.

III.F.6. Where will the Point of Compliance be located?

Introduction to the alternatives. We are presenting four alternatives for comment prior to determining the location of the point of compliance. They are presented in the proposed regulatory text (see proposed § 197.37) and are discussed here in no particular order of preference. For convenience, we refer to them as Alternatives 1, 2, 3, and 4, respectively.

We note that Alternatives 2 and 3 rely upon our current knowledge of ground water flow and use in the region. As discussed above, we are also proposing a method for proceeding under Alternatives 2 and 3, if further knowledge changes the understanding of the flow of the region's ground water or the location of the highest concentrations of radionuclides.

Alternatives in proposed § 197.37. Alternative 1 would establish a "controlled area." In this case, we would define the extent of the controlled area (in proposed § 197.12) as it is in 40

CFR part 191 (with the substitution of the term “repository footprint” for the original wording, “outer boundary of the original location of the radioactive wastes in a disposal system”):

(1) a surface area, identified by passive institutional controls, that encompasses no more than 100 square kilometers and extends horizontally no more than five kilometers in any direction from the repository footprint; and (2) the subsurface underlying the surface area.

The Department would determine where on the controlled area’s boundary to place the point of compliance based upon the projected direction of ground water flow and the expected locations of the highest concentrations of radionuclides.

As mentioned earlier, this approach would be consistent with 40 CFR part 191 and would, therefore, maintain consistency with the generic standards which apply to WIPP, GCD, and any future disposal system for SNF, HLW, and transuranic radioactive waste which is subject to 40 CFR part 191. (As described earlier, the GCD facility is a complex of 120-feet deep boreholes, located within NTS, which contains disposed transuranic radioactive waste and WIPP is a geologic disposal system, in New Mexico, for defense-related transuranic radioactive waste.) While this alternative would not provide explicitly for consideration of site-specific factors in determining the size of the controlled area, it would ensure that the boundary of the controlled area would not extend substantially beyond Yucca Mountain itself. This alternative would have the effect of providing natural topographic constraints on access to ground water within the controlled area. Therefore, it would provide a safeguard against use of ground water within the controlled area during the compliance period.

In Alternative 2, we would specify the location of the point of compliance. In this case, the point of compliance would be located near the intersection of U.S. Route 95 and Nevada State Route 373, commonly referred to as Lathrop Wells (Lathrop Wells is actually an area within the

Town of Amargosa Valley and is the location closest to Yucca Mountain where the general population currently consumes water). We have found that the depth to the water currently withdrawn for domestic use within the Town of Amargosa Valley ranges from a few meters in the southern parts of the town to 110 meters near Lathrop Wells (see the BID). This alternative would put the point of compliance near the currently assumed location of the RMEI.

In Alternative 3, we would establish an area located about 30 km south of Yucca Mountain within which DOE and NRC would identify a specific point as the point of compliance. The area would be bounded by Frontier Street on the north, Nevada State Route 373 on the east, the Nevada-California border on the south/southwest, and Casada Way on the west. About 75% of the current population and about 60% of the current water-supply wells in what we understand to be the downgradient direction from Yucca Mountain are within this area. This is an area where it is relatively easy to access ground water (see the BID). This option would, therefore, provide direct protection for most of the population currently using drinking water from the alluvial aquifer.

In Alternative 4, the Department, with the consent of NRC, would establish a controlled area outside of which the ground water standards would apply. Its size would be determined by DOE (without exceeding the limits set by us). This controlled area would be a combination of Alternative 1and site-specific considerations for Yucca Mountain. The site-specific consideration is the proximity of the repository footprint and NTS. The boundary of the controlled area could be no more than five kilometers from the footprint (the same limit applied in Alternative 1), except in those cases where the five kilometers is located within the NTS. In that case, DOE may extend the controlled area to include all or part of the NTS.

We base this alternative, in part, upon the fact that NTS has existed under the control of DOE for about 50 years. Another basis is that we believe that future generations will be aware of the extensive, well-publicized nuclear activities that occurred there. This will likely increase the effectiveness of the passive institutional controls, as discussed below. The NTS is well-known around the world for many reasons but most notably for the approximately 900 tests of nuclear weapons conducted there. This makes NTS unique in the Western Hemisphere because of the resultant presence of hundreds of millions of curies of radionuclides (see the BID). This will presumably lead the Federal government to document the extent of radionuclide contamination and the activities which occurred there, including the Yucca Mountain disposal system, more thoroughly and retain records for longer periods than might occur elsewhere.

To repeat for clarification, the conceptual difference between Alternatives 1 and 4 and Alternatives 2 and 3 is that in Alternatives 1 and 4, we will define an area surrounding the repository outside of which the ground water standards would apply, whereas for Alternatives 2 and 3, we will specify limited areas downgradient from the repository within which DOE and NRC must place the point of compliance.

We request comment upon all of the alternatives discussed above. Commenters should address the effectiveness of these or other alternatives for protecting ground water, including consideration of site-specific characteristics and reasonable methods of implementing the alternatives.